Proposed rules include new rules, amendments to existing rules, and repeals of existing rules. A state agency shall give at least 30 days' notice of its intention to adopt a rule before it adopts the rule. A state agency shall give all interested persons a reasonable opportunity to submit data, views, or arguments, orally or in writing (Government Code, Chapter 2001).

Symbols in proposed rule text. Proposed new language is indicated by underlined text. [~~Square brackets and strikethrough~~] indicate existing rule text that is proposed for deletion. "(No change)" indicates that existing rule text at this level will not be amended.

TITLE 1. ADMINISTRATION

PART 2. TEXAS ETHICS COMMISSION

CHAPTER 16. FACIAL COMPLIANCE REVIEWS AND AUDITS

1 TAC §16.12

The Texas Ethics Commission (the Commission) proposes new Texas Ethics Commission Rule §16.12, concerning Facial Review of Total Amount of Political Contributions Maintained, which would provide clarification in the facial compliance review process.

Section 571.069 of the Government Code requires the Commission to review randomly selected reports "for facial compliance" and allows the Commission to perform a complete audit or initiate a preliminary review (enforcement action) in certain circumstances. This includes a deficiency in the total amount of political contributions maintained as of the last day of the reporting period, which is required to be disclosed on the cover sheet of a campaign finance report under §254.034(a)(8) of the Election Code.

Commission Rules §20.50 states, in part, that the total amount of political contributions maintained includes the balance on deposit in banks and other depository institutions, the present value of any investments that can readily be converted to cash, and the balance of political contributions in an online fundraising account. In short, the amount of contributions maintained is a filer's bank balance as of the last day of the reporting period. A filer's bank statements can show whether the reported bank balance is correct. However, using beginning and ending balances as part of a facial compliance review has often revealed discrepancies in contributions and expenditures, and Commission staff have requested additional information from filers to identify the causes of those discrepancies. New rule §16.12 would clarify that bank statements showing that the amount of contributions maintained was reported correctly ends staff's review of a discrepancy in the reported bank balance, but additional discrepancies in the report may exist that staff may further review.

Seana Willing, Executive Director, has determined that for the first five-year period the proposed new rule is in effect there will be no fiscal implications for state or local government as a result of enforcing or administering the proposed new rule.

The Executive Director has also determined that for each year of the first five years the proposed new rule is in effect the public benefit will be clarity in the facial compliance review process. There will not be an effect on small businesses, micro-businesses, or rural communities. There is no anticipated economic cost to persons who are required to comply with the proposed new rule.

The Executive Director has determined that during the first five years that the proposed new rule is in effect, it will not: create or eliminate a government program; require the creation of new employee positions or the elimination of existing employee positions; require an increase or decrease in future legislative appropriations to the agency; require an increase or decrease in fees paid to the agency; expand, limit, or repeal an existing regulation; increase or decrease the number of individuals subject to the rules' applicability; or positively or adversely affect this state's economy. The rule is new and therefore creates a new regulation. However, it is needed to clarify facial compliance procedures conducted under §571.069 of the Government Code, in response to the public's concerns with the process.

The Texas Ethics Commission invites comments on the proposed new rule from any member of the public. A written statement should be emailed to public_comment@ethics.state.tx.us, or mailed or delivered to Seana Willing, Texas Ethics Commission, P.O. Box 12070, Austin, Texas 78711-2070, or by facsimile (FAX) to (512) 463-5777. A person who wants to offer spoken comments to the commission concerning the proposed new rule may do so at any commission meeting during the agenda item relating to the proposed new rule. Information concerning the date, time, and location of commission meetings is available by telephoning (512) 463-5800 or on the Texas Ethics Commission's website at www.ethics.state.tx.us.

New rule §16.12 is proposed under Texas Government Code §571.062, which authorizes the commission to adopt rules to administer Title 15 of the Election Code.

The proposed new rule affects §571.069 of the Government Code.

§16.12. Facial Review of Total Amount of Political Contributions Maintained.

(a) In this section "expected total political contributions maintained" for a report subject to review is the total amount of political contributions maintained disclosed on the previous report and all monetary political contributions, loans, and credits, less all expenditures from political contributions disclosed on the report that is subject to review, excluding the purchase of investments that can be readily converted to cash.

(b) When there is a difference greater than the threshold set by §20.50(c) of this title (relating to Total Political Contributions Maintained) between the total amount of political contributions maintained disclosed in a report and the expected total political contributions maintained, the commission may request from the filer the bank statement showing the balance as of the last day of the reporting period for each account in which political contributions are maintained.

(c) Producing the requested bank statements that show the total amount of political contributions was accurately reported in the report that is subject to review is sufficient to end the review of the total amount of political contributions maintained as disclosed in the report.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 18, 2018.

TRD-201805481
Seana Willing
Executive Director
Texas Ethics Commission
Earliest possible date of adoption: February 3, 2019
For further information, please call: (512) 463-5800

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CHAPTER 18. GENERAL RULES CONCERNING REPORTS

1 TAC §18.31

The Texas Ethics Commission (the Commission) proposes new Texas Ethics Commission Rule §18.31, regarding the adjustment of reporting thresholds, under section 571.064(b) of the Government Code.

Section 571.064(b) of the Government Code requires the Commission to annually adjust reporting thresholds upward to the nearest multiple of $10 in accordance with the percentage increase for the previous year in the Consumer Price Index for Urban Consumers published by the Bureau of Labor Statistics of the United States Department of Labor. The laws under the Commission's authority that include reporting thresholds are Title 15 of the Election Code (campaign finance law), Chapter 305 of the Government Code (lobby law), Chapter 572 of the Government Code (personal financial statements), and Chapters 302 and 303 of the Government Code (speaker election, governor for a day, and speaker's reunion day ceremony reports). Adjustments to the campaign finance reporting thresholds would affect every campaign finance filer in Texas, including statewide and local candidates, officeholders, political committees, direct expenditure reporters, and caucuses. Similarly, adjustments to lobby and personal financial statement thresholds would affect all registered lobbyists and personal financial statement filers. The new rule identifies each reporting threshold by citation and description and shows the original and adjusted amounts. If adopted, the rule is intended to be effective on January 1, 2020.

Seana Willing, Executive Director, has determined that enforcing and administering the proposed new rule will have a fiscal impact on the agency's budget of $141,875 for the first year only to make enhancements to the agency's electronic filing software and database, thus requiring an increase of that amount in the legislative appropriation for the 2020-2021 biennium.

The Executive Director has also determined that for each year of the first five years the proposed new rule is in effect the public benefit will be higher reporting thresholds as required by the Texas Government Code and potentially reduced burdens on completing reports. There will not be an effect on small businesses, micro-businesses, or rural communities. There is no anticipated economic cost to persons who are required to comply with the proposed new rule.

The Executive Director has determined that during the first five years that the proposed new rule is in effect, it will: not create or eliminate a government program; not require the creation of new employee positions or the elimination of existing employee positions; require an increase in future legislative appropriations to the agency; require an increase or decrease in fees paid to the agency; expand, limit, or repeal an existing regulation; not increase or decrease the number of individuals subject to the rules' applicability; or not positively or adversely affect this state's economy. The rule is new and therefore creates a new regulation. It is required by section 571.064(b) of the Government Code.

The Texas Ethics Commission invites comments on the proposed new rule from any member of the public. A written statement should be emailed to public_comment@ethics.state.tx.us, or mailed or delivered to Seana Willing, Texas Ethics Commission, P.O. Box 12070, Austin, Texas 78711-2070, or by facsimile (FAX) to (512) 463-5777. A person who wants to offer spoken comments to the commission concerning the proposed new rule may do so at any commission meeting during the agenda item relating to the proposed new rule. Information concerning the date, time, and location of commission meetings is available by telephoning (512) 463-5800 or on the Texas Ethics Commission's website at www.ethics.state.tx.us.

New rule §18.31 is proposed under Texas Government Code §571.062, which authorizes the commission to adopt rules to administer Title 15 of the Election Code.

The proposed new rule §18.31 affects Title 15 of the Election Code, and Chapters 305 and 572 of the Government Code.

§18.31. Adjustments to Reporting Thresholds.

(a) Pursuant to section 571.064 of the Government Code, the reporting thresholds are adjusted as follows:
Figure 1: 1 TAC §18.31(a)
Figure 2: 1 TAC §18.31(a)
Figure 3: 1 TAC §18.31(a)
Figure 4: 1 TAC §18.31(a)

(b) The effective date of this rule is January 1, 2020.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 18, 2018.

TRD-201805488
Seana Willing
Executive Director
Texas Ethics Commission
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For further information, please call: (512) 463-5800

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CHAPTER 24. RESTRICTIONS ON CONTRIBUTIONS AND EXPENDITURES APPLICABLE TO CORPORATIONS AND LABOR ORGANIZATIONS

1 TAC §24.18

The Texas Ethics Commission (the Commission) proposes new Texas Ethics Commission Rule §24.18, regarding the designation of a corporate expenditure made under section 253.100(a) of the Election Code. The rule was petitioned under section 2001.021 of the Government Code. The following is a statement from a subcommittee of the members of the Commission regarding the petition.

Our analysis begins with Tex. Election Code §253.094, which provides that a corporation or labor organization may not make a political contribution not authorized by that subchapter. Therefore, the basic rule is that there is a general prohibition against political contributions in Texas elections by corporations and labor unions.

Tex. Election Code §253.100(a) authorizes an exception to the general prohibition by allowing a corporation, acting alone or with one or more other corporations, to make one or more political expenditures to finance the establishment or administration of a GPAC. Section 253.100(b) allows corporate political expenditures to finance the solicitation of political contributions to the GPAC by shareholders and employees. Section 253.100(c) authorizes labor unions to engage in any activity authorized for a corporation in that section. So, both corporations and labor unions may make expenditures to GPACs *for the limited purposes of financing the establishment or administration of the GPAC* under §253.100.

Mr. Fischer's proposed rule is based on the Texas Court of Criminal Appeals case of *Ex parte Ellis,* 309 S.W. 3d 71 (2010), which held that §253.100 was not unconstitutionally vague, and in which the Court stated "(t)here is no such thing as a legal undesignated corporate political contribution... A corporation must designate the purpose of the political contribution by...making expenditures for the maintenance and operation of a corporate political committee." *Id.* at 88. Following on the logic of the Court of Criminal Appeals that there cannot be a legal undesignated corporate political contribution (and presumably seeking to avoid the potential civil and criminal liability for such an undesignated - and possibly illegal - contribution), Mr. Fischer proposes a rule that provides that a corporate expenditure to a GPAC will be automatically designated as restricted to the establishment, administration, maintenance, or operation of a GPAC if one of three things occurs:

1. There is a contemporaneous written instruction that the expenditure is so restricted;

2. The negotiable instrument conveying the contribution indicates that the entity is a corporation; or

3. The GPAC accepting the contribution reports the contribution as from a corporation or labor organization.

The subcommittee views this proposed rule as a wise, common-sense solution to the issue of a possibly undesignated contribution, and one that assumes members of the regulated community are acting in compliance with the Election Code in the absence of evidence to the contrary. Therefore, the subcommittee recommends that the Commission publish Mr. Fischer's proposed rule.

Seana Willing, Executive Director, has determined that for the first five-year period the proposed rule is in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the proposed new rule.

The Executive Director has also determined that for each year of the first five years the proposed new rule is in effect, the public benefit will be clarity regarding the manner in which political expenditures are designated in accordance with §253.100(a) of the Election Code. There will not be an effect on small businesses, micro-businesses, or rural communities. There is no anticipated economic cost to persons who are required to comply with the proposed new rule.

The Executive Director has determined that during the first five years that the proposed new rule is in effect, it will not: create or eliminate a government program; require the creation of new employee positions or the elimination of existing employee positions; require an increase or decrease in fees paid to the agency; expand, limit, or repeal an existing regulation; increase or decrease the number of individuals subject to the rules' applicability; or positively or adversely affect this state's economy. The rule is a new regulation.

The Texas Ethics Commission invites comments on the proposed new rule from any member of the public. A written statement should be emailed to public_comment@ethics.state.tx.us, or mailed or delivered to Seana Willing, Texas Ethics Commission, P.O. Box 12070, Austin, Texas 78711-2070, or by facsimile (FAX) to (512) 463-5777. A person who wants to offer spoken comments to the commission concerning the proposed new rule may do so at any commission meeting during the agenda item relating to the proposed new rule. Information concerning the date, time, and location of commission meetings is available by telephoning (512) 463-5800 or on the Texas Ethics Commission's website at www.ethics.state.tx.us.

New rule §24.18 is proposed under Texas Government Code §571.062, which authorizes the commission to adopt rules concerning the laws administered and enforced by the commission.

The proposed new rule §24.18 affects Texas Election Code §253.100.

§24.18. Designation of Contribution for Administrative Purposes.

Any of the following will serve to designate a corporate expenditure as restricted to the establishment, administration, maintenance, or operation of a general-purpose committee:

(1) A contemporaneous written instruction that the expenditure is restricted to the administration, maintenance, or operation of the committee accepting the expenditure;

(2) The negotiable instrument conveying the contribution contains language indicating that the entity is a corporation, including but not limited to "Inc.," "Incorporated," "Corp.," or "Corporation;" or

(3) The general-purpose committee accepting the contribution reports the contribution as monetary contribution or monetary support from a corporation or labor organization on the committee's campaign finance report.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Seana Willing
Executive Director
Texas Ethics Commission
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For further information, please call: (512) 463-5800

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CHAPTER 34. REGULATION OF LOBBYISTS SUBCHAPTER C. COMPLETING THE REGISTRATION FORM

1 TAC §34.77

The Texas Ethics Commission (the Commission) proposes new Texas Ethics Commission Rule §34.77, which would require a lobbyist to disclose on the lobby registration (Form REG) filed with the Commission the number assigned to the lobbyist's active registration under the Foreign Agents Registration Act (FARA) that is filed with the U.S. Attorney General (AG).

This rule is published in response to a request from two members of the Texas Legislature and is intended to further transparency. FARA requires an agent of a foreign principal to register with the AG (as head of the U.S. Department of Justice) by filing a Registration Statement, including disclosure of income from the foreign principal and the scope of activities as an agent. A FARA Registration Statement or a Short Form Registration Statement is assigned a registration number that is displayed on the registration and other associated filings. The proposed new rule would require a person who registers with the Commission as a lobbyist to disclose their FARA registration number on their lobbyist registration. Once the FARA Registration Statement is terminated, the requirement to disclose the FARA registration number on the lobbyist registration would cease.

Seana Willing, Executive Director, has determined that enforcing and administering the proposed new rule will have a fiscal impact on the agency's budget of $10,000 for the first year only.

The Executive Director has also determined that for each year of the first five years the proposed new rule is in effect, the public benefit will be public disclosure in Texas that a registrant has separately registered under FARA. There will not be an effect on small businesses, micro-businesses, or rural communities. There is no anticipated economic cost to persons who are required to comply with the proposed new rule.

The Executive Director has determined that during the first five years that the proposed new rule is in effect, it will not: create or eliminate a government program; require the creation of new employee positions or the elimination of existing employee positions; require an increase or decrease in fees paid to the agency; expand, limit, or repeal an existing regulation; increase or decrease the number of individuals subject to the rules' applicability; or positively or adversely affect this state's economy. The rule is a new regulation and would require a one-time $10,000 increase in the Commission's legislative appropriations.

The Texas Ethics Commission invites comments on the proposed new rule from any member of the public. A written statement should be emailed to public_comment@ethics.state.tx.us, or mailed or delivered to Seana Willing, Texas Ethics Commission, P.O. Box 12070, Austin, Texas 78711-2070, or by facsimile (FAX) to (512) 463-5777. A person who wants to offer spoken comments to the commission concerning the proposed new rule may do so at any commission meeting during the agenda item relating to the proposed new rule. Information concerning the date, time, and location of commission meetings is available by telephoning (512) 463-5800 or on the Texas Ethics Commission's website at www.ethics.state.tx.us.

New rule §34.77 is proposed under Texas Government Code §571.062, which authorizes the commission to adopt rules concerning the laws administered and enforced by the commission.

The proposed new rule §34.77 affects Chapter 305 of the Government Code.

§34.77. Disclosure of Registration under Foreign Agents Registration Act.

The registration of any person who has also filed an active registration statement under the Foreign Agents Registration Act of 1938, as amended (22 U.S.C. §611 et seq.), must include the registration number assigned to the registration statement by the United States Attorney General until the registration statement is terminated.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Seana Willing
Executive Director
Texas Ethics Commission
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For further information, please call: (512) 463-5800

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TITLE 4. AGRICULTURE

PART 1. TEXAS DEPARTMENT OF AGRICULTURE

CHAPTER 7. PESTICIDES SUBCHAPTER D. USE AND APPLICATION

4 TAC §7.30

The Texas Department of Agriculture (Department) proposes the amendment of Title 4, Part 1, Chapter 7, Subchapter D, §7.30, relating to Classification of Pesticides. The proposal is made in order to add mandatory training prior to the application of 3,6-Dichloro-o-anisic acid (dicamba), as required by the Environmental Protection Agency (EPA), and 2,4-dichlorophenoxyacetic acid (2,4-D), in order to reduce the potential for misapplication of the products which could cause damage to sensitive crops which may be exposed to the pesticides.

The amendments are also proposed to align use requirements for applicators of dicamba with the product label which was revised by the Environmental Protection Agency to require training for applicators prior to over-the-top applications of the product. Applications of 2,4-D or dicamba by untrained applicators can cause significant economic damage to non-tolerant cotton, grapes, peanuts and other non-tolerant crops grown in the state exposed to the state-limited-use pesticides.

By requiring yearly product training, applicators will maintain current knowledge of topics including application timing, nozzle re-

quirements/selection, wind speed, ground speed, boom height, tank cleanout, sensitive crops and buffer zone requirements, weather conditions, and drift, volatility and inversion. Training will ensure that applicators are knowledgeable of proper application techniques and compliance with label requirements in order to best protect surrounding sensitive crops.

Dale R. Scott, Director for Environmental and Biosecurity Programs, has determined there will be minimal fiscal impact for state government as a result of administering the proposed change. There will be no significant fiscal impact to the Department. Texas A&M AgriLife Extension Service (AgriLife) is currently a provider of continuing education units (CEU) for various pesticide training courses. During the 2018 growing season, AgriLife provided training to over 6,700 pesticide applicators regarding the use and application of dicamba. AgriLife will continue to provide continuing education courses for dicamba, and will begin offering training for 2,4-D. AgriLife currently receives funds to subsidize the costs of training in the form of grants from the Department, and funds from industry stakeholders. It is not anticipated that there will be a significant state fiscal impact associated with additional training regarding application of 2,4-D and dicamba. There will be no fiscal impact on local government.

Mr. Scott has also determined that for each year of the first five years the proposal is in effect, the public benefit will be the prevention of misapplications of herbicides causing economic damage to sensitive crops. In 2017, over 7 million acres were planted in Texas, all of which could be susceptible to the active ingredients of 2,4-D or dicamba.

There will be minimal adverse fiscal impact on individuals, and small or micro businesses as a result of the proposed rule changes. Pesticide applicators are currently required to meet continuing education requirements as part of their recertification process. The proposed rules will allow applicators to use credit hours obtained through additional 2,4-D and dicamba training toward satisfying continuing education units, and will not increase the hours currently required to meet an applicator's continuing education requirements. Additionally, the cost of 2,4-D and dicamba training courses will be largely offset by industry stakeholders, including manufacturers. There will be no anticipated negative fiscal impact on rural communities.

Mr. Scott has provided the following information related to the government growth impact statement, as required pursuant to Texas Government Code, §2001.021. As a result of implementing the proposal, for the first five years the proposed rule is in effect:

(1) no new or current government or Department programs will be created or eliminated;

(2) no employee positions will be created, nor will any existing Department staff positions be eliminated; and

(3) there will not be an increase or decrease in future legislative appropriations to the Department.

Additionally, Mr. Scott has determined that for the first five years the proposed rule is in effect:

(1) there will be no increase or decrease in fees paid to the Department;

(2) there will be new regulations created by the proposal;

(3) there will be no increase or decrease to the number of individuals subject to the proposal, as all pesticide applicators currently subject to the rule must comply with pesticide label requirements; and

(4) the proposal is not anticipated to have an adverse effect on the Texas economy.

Written comments on the proposal may be submitted to Dale R. Scott, Director for Environmental and Biosecurity Programs, Texas Department of Agriculture, P.O. Box 12847, Austin, Texas 78711 or by email to *rulecomments@TexasAgriculture.gov*. Comments must be received no later than February 1, 2019.

The amendments are proposed under §76.004 of the Texas Agriculture Code, which provides the Department with the authority to adopt rules related to the labeling requirements for pesticides required to be registered under Chapter 76.

The code affected by the proposal is the Texas Agriculture Code, Chapter 76.

§7.30. Classification of Pesticides.

(a) State-Limited-Use Pesticides Defined by Active Ingredient.

(1) - (4) (No change.)

(5) The following are restrictions on use and distribution of State-Limited-Use pesticides and regulated herbicides:

(A) - (C) (No change.)

(D) A person may not apply 2,4-dichlorophenoxyacetic acid (2,4-D) on a transgenic auxin herbicide tolerant crop unless the person has attended an auxin training course approved by the Department prior to application.

(i) One (1) 2,4-D continuing education unit (CEU) shall be required annually and is valid for one year from the date of course attendance.

(ii) Courses shall be approved by the Department and may not be less than 50 minutes in length for each active ingredient. No more than one (1) CEU will be assigned for any 50 minutes of actual instruction time in Laws and Regulations as described in §7.24 of this title, relating to applicator recertification.

(iii) Each course shall include topics on: application timing, nozzle requirements/selection, wind speed, ground speed, boom height, tank cleanout, sensitive crops and buffer zone requirements, weather conditions, and drift, volatility and inversion.

(E) A person may not apply 3,6-Dichloro-o-anisic acid (dicamba) on a transgenic auxin herbicide tolerant crop unless the person has attended an auxin training course approved by the Department prior to application.

(i) One (1) dicamba continuing education unit (CEU) shall be required annually and is valid for one year from the date of course attendance.

(ii) Courses shall be approved by the Department and may not be less than 50 minutes in length for each active ingredient. No more than one (1) CEU will be assigned for any 50 minutes of actual instruction time in Laws and Regulations as described in §7.24 of this title, relating to applicator recertification.

(iii) Each course shall include topics on: application timing, nozzle requirements/selection, wind speed, ground speed, boom height, tank cleanout, sensitive crops and buffer zone requirements, weather conditions, and drift, volatility and inversion.

(b) - (c) (No change.)

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 17, 2018.

TRD-201805447
Jessica Escobar
Assistant General Counsel
Texas Department of Agriculture
Earliest possible date of adoption: February 3, 2019
For further information, please call: (512) 463-4075

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CHAPTER 30. COMMUNITY DEVELOPMENT

SUBCHAPTER A. TEXAS COMMUNITY DEVELOPMENT BLOCK GRANT PROGRAM

The Texas Department of Agriculture (Department) proposes the amendment of Chapter 30, Subchapter A, Division 1, §30.3, relating to Program Overview; the repeal of Subchapter A, Division 3, §30.64, relating to the Community Enhancement Fund (CEF); proposes new Subchapter A, Division 3, §30.64, relating to the Fire, Ambulance & Services Truck (FAST) Fund; and amendments to Subchapter A, Division 3, §30.52, relating to the Texas Capital Fund--Real Estate and Infrastructure Development Programs. The proposed rules clarify current program requirements, repeal a fund category no longer administered by the Department, and include rules for a new program fund administered by the Department.

Section 30.64 is proposed for repeal to remove reference to the Community Enhancement Fund, a fund category under the Community Development Block Grant (CDBG) Program which is no longer administered by the Department. New §30.64 adds rules related to the Fire, Ambulance & Services Truck (FAST) Fund, a new category eligible for CDBG funding beginning in Program Year 2019. The proposed rules are related to FAST application cycle, eligibility requirements, and selection procedures. Amendments to §30.3 reflect the changes made as a result of the proposed repeal and new rules.

The proposed amendments to §30.52 clarify grant application criteria and provide a more efficient application evaluation process in order to provide economic development assistance in an equitable manner.

Suzanne Barnard, Director for CDBG Programs, has determined that for the first five years the rules are in effect, there will be no adverse fiscal implications for state or local governments as a result of the proposal.

Ms. Barnard has also determined that for each year of the first five years the rules are in effect, the public benefit anticipated as a result of administering the rules will be enhanced accessibility to emergency response vehicles in underserved communities. There will be no adverse economic effect on micro-businesses, small businesses or individuals as a result of the proposal. There will be no adverse impact to rural communities.

Ms. Barnard has provided the following information related to the government growth impact statement, as required pursuant to Texas Government Code, §2001.021. As a result of implementing the proposal, for the first five years the proposed rule is in effect:

(1) no new or current government or Department programs will be created or eliminated;

(2) no employee positions will be created, nor will any existing Department staff positions be eliminated; and

(3) there will not be an increase or decrease in future legislative appropriations to the Department.

Additionally, Ms. Barnard has determined that for the first five years the proposed rule is in effect:

(4) there will be no increase or decrease in fees paid to the Department;

(5) there will be new regulations created by the proposal;

(6) there will be no increase or decrease to the number of individuals subject to the proposal, as communities in Texas remain subject to CDBG program rules and eligibility requirements; and

(7) the proposal is not anticipated to have an adverse effect on the Texas economy.

Written comments on the proposal may be submitted to Suzanne Barnard, Director for CDBG Programs, Texas Department of Agriculture, P.O. Box 12847, Austin, Texas 78711, or by email to *RuleComments@TexasAgriculture.gov*. Comments must be received no later than February 1, 2019.

DIVISION 1. GENERAL PROVISIONS

4 TAC §30.3

The proposal is made under Texas Government Code §487.051, which designates the Department as the agency to administer the federal community development block grant non-entitlement program, and §487.052, which provides authority for the Department to adopt rules as necessary to implement Chapter 487.

The code affected by the proposal is Texas Government Code, Chapter 487.

§30.3. Program Overview.

(a) Fund categories. TxCDBG Program assistance is available through the following seven fund categories.

(1) - (6) (No change.)

(7) Fire, Ambulance & Services Truck (FAST) Fund provides assistance to rural communities for fire, ambulance, and similar emergency vehicle response needs. [~~Community Enhancement Fund (CEF) is designed to stimulate a community's economic development efforts and improve self-sufficiency, while providing a benefit that potentially enhances the overall quality of life for all residents within a community.~~]

(b) (No change.)

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 19, 2018.

TRD-201805544

Jessica Escobar
Assistant General Counsel
Texas Department of Agriculture
Earliest possible date of adoption: February 3, 2019
For further information, please call: (512) 463-4075

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DIVISION 3. ADMINISTRATION OF PROGRAM FUNDS

4 TAC §30.52, §30.64

The proposal is made under Texas Government Code §487.051, which provides the Department authority to administer the state's community development block grant non-entitlement program, and §487.052, which provides authority for the Department to adopt rules as necessary to implement Chapter 487.

The code affected by the proposal is Texas Government Code, Chapter 487.

§30.52. Texas Capital Fund--Real Estate and Infrastructure Development Programs.

(a) Application cycle. Applications for Real Estate and Infrastructure funding are accepted on a quarterly [~~monthly~~] basis. [~~Applications not selected for award may be resubmitted for consideration in subsequent rounds.~~]

(b) - (c) (No change.)

(d) Selection procedures.

(1) Preliminary review and scoring of applications. The department will review and score applications based on selection criteria which focus on the following factors (detailed application and scoring information are available in the TCF application guidelines):

(A) Job creation criteria:

(i) cost-per-job;

(ii) wage impact; and

(iii) primary jobs created/retained;

~~*[(ii)* job impact;]~~

~~*[(iii)* wage impact; and]~~

~~*[(iv)* primary jobs created/retained;]~~

(B) (No change.)

(C) Readiness to proceed:

(i) executed company-contractor agreement; and

(ii) environmental clearance.

~~[(C) Return on investment.]~~

(2) - (3) (No change.)

(4) Tie score. In the event of a tie score, tying applications are ranked from highest to lowest based on the lowest proposed cost-per-job. If a tie still exists after applying the first tie-breaker criteria, then applications are ranked from highest to lowest based on the lowest per capita income [~~greatest proposed job impact~~].

(e) - (g) (No change.)

§30.64. Fire, Ambulance & Services Truck (FAST) Fund.

(a) Application cycle. Contingent on the availability of funding, applications for the Fire, Ambulance & Services Truck (FAST) Fund will be accepted annually, during a period specified by the department. Funding for this program will be provided from deobligated funds and other external sources, when available.

(b) Eligible vehicles. Eligible FAST vehicles include:

(1) fire trucks (all types);

(2) ambulances and similar emergency medical vehicles;

(3) jaws of life and similar rescue equipment;

(4) rescue boats and similar specialized emergency vehicles; and

(5) other vehicles identified in the application guidelines.

(c) Ineligible vehicles. Ineligible FAST vehicles include:

(1) police cars and other vehicles primarily used by law enforcement; and

(2) vehicles used primarily for the general conduct of government.

(d) Selection procedures. Applications will be evaluated by the department based on selection criteria which includes the following factors (detailed application and scoring information is available in the application guidelines):

(1) community need:

(A) poverty rate of applicant (cities compared to cities, and counties compared to counties);

(B) per capita income (cities compared to cities, and counties compared to counties);

(2) previous TxCDBG funding; and

(3) past performance on TxCDBG grants.

(e) Tie score. In the event of a tie score, tying applications are ranked from highest to lowest based on the highest percentage of low-to-moderate income persons benefitting from the proposed project.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 19, 2018.

TRD-201805546
Jessica Escobar
Assistant General Counsel
Texas Department of Agriculture
Earliest possible date of adoption: February 3, 2019
For further information, please call: (512) 463-4075

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4 TAC §30.64

The proposal is made under Texas Government Code §487.051, which provides the Department authority to administer the state's community development block grant non-entitlement program, and §487.052, which provides authority for the Department to adopt rules as necessary to implement Chapter 487.

The code affected by the proposal is Texas Government Code, Chapter 487.

§30.64. Community Enhancement Fund (CEF).

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 19, 2018.

TRD-201805545
Jessica Escobar
Assistant General Counsel
Texas Department of Agriculture
Earliest possible date of adoption: February 3, 2019
For further information, please call: (512) 463-4075

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PART 2. TEXAS ANIMAL HEALTH COMMISSION

CHAPTER 51. ENTRY REQUIREMENTS

4 TAC §51.9

The Texas Animal Health Commission (Commission) proposes amendments to Chapter 51, entitled "Entry Requirements," in 4 TAC §51.9. The purpose of these amendments to Chapter 51 is to remove the Brucellosis test requirement for farmed exotic cervidae to enter the state.

The Commission has had a requirement that exotic cervidae entering Texas be Brucellosis tested. The United States Animal Health Association (USAHA) issued a Resolution that urges that states remove a Brucellosis test requirement for these exotic cervidae moving in interstate commerce. The reason for this request is there are no known reservoirs for Brucellosis outside of the Designated Surveillance Area (DSA) which is located in the Greater Yellowstone Area (GYA) in the states of Montana, Idaho and Wyoming and therefore, the testing requirement to enter Texas is being removed for farmed exotic cervidae. However, for any farmed exotic cervidae that have resided within the DSA of the GYA, they are still required to be tested prior to entry into Texas. The requirement to be Brucellosis tested still applies if the exotic cervidae has been a free ranging exotic cervidae from any state.

FISCAL NOTE

Mrs. Larissa Schmidt, Chief of Staff, Texas Animal Health Commission, has determined that for the first five-year period the rules are in effect, there will be no significant additional fiscal implications for state or local government because of enforcing or administering the rules.

REGULATORY ANALYSIS

Public Benefit: Ms. Schmidt has also determined that for each year of the first five (5) years the rules are in effect, the public benefit anticipated because of enforcing the rules will be removing a requirement to enter Texas.

Local Employment Impact Statement: In accordance with Texas Government Code §2001.022, this agency has determined that the proposed rules will not impact local economies and, therefore, did not file a request for a local employment impact statement with the Texas Workforce Commission.

Major Environmental Rule: The Commission has determined that Government Code, §2001.0225 (Regulatory Analysis of Major Environmental Rules), does not apply to the proposed rule.

Takings Assessment: The agency has determined that the proposed governmental action will not affect private real property. The proposed amendments are an activity related to the handling of animals, including requirements for testing, movement, inspection, identification, reporting of disease, and treatment, in accordance with Title 4 TAC §59.7, and are, therefore, compliant with the Private Real Property Preservation Act in Government Code, Chapter 2007.

EIS: The Commission has determined that the animal agricultural industries meet the statutory definition of a small or microbusiness (Government Code, Chapter 2006), and that the proposed rule would affect rural communities (as defined by Government Code, Chapter 2006); however, the Commission also has determined that the rule as proposed will not result in adverse economic impacts to small and microbusinesses or rural communities because it is for animals entering the state and not from the state.

RFA: The proposed rule does minimize adverse impacts on affected small businesses and/or rural communities located in Texas by allowing an easier standard to meet for exotic cervidae entering the state.

GGIS: In compliance with the requirements of Government Code, §2001.0221, the Commission has prepared the following Government Growth Impact Statement (GGIS). The rule as proposed, if adopted:

(1) will neither create nor eliminate a government program;

(2) will not result in an increase or decrease in the number of full-time equivalent employee needs;

(3) will not result in a need for additional General Revenue funding;

(4) will not affect the amount of any fee;

(5) will modify a pre-existing regulation;

(6) will not expand an existing regulation;

(7) may increase the number of individuals subject to regulation; and

(8) will not adversely affect the state's economy.

Rule Reduction Statement: The commission has determined that the rule as proposed follows the legislative requirement that the commission shall protect all livestock, exotic livestock, domestic fowl, and exotic fowl within the state from regulatory diseases. It does not impose a direct cost on regulated persons within the state but rather removes a regulatory disease compliance requirement, and therefore it is not necessary to repeal or amend any other existing rule.

REQUEST FOR COMMENT

Comments regarding the proposed amendments may be submitted to Amanda Bernhard, Texas Animal Health Commission, 2105 Kramer Lane, Austin, Texas 78758, by fax at (512) 719-0719 or by e-mail at *comments@tahc.texas.com.*

STATUTORY AUTHORITY

The amendments are proposed under the following statutory authority as found in Chapter 161 of the Texas Agriculture Code. The Commission is vested by statute, §161.041(a), with the re-

quirement to protect all livestock, domestic animals, and domestic fowl from disease. The Commission is authorized, through §161.041(b), to act to eradicate or control any disease or agent of transmission for any disease that affects livestock.

Pursuant to §161.054, and entitled Regulation of Movement of Animals, "[t]he Commission, by rule, may regulate the movement of animals. The Commission may restrict the intrastate movement of animals even though the movement of the animals is unrestricted in interstate or international commerce."

Pursuant to §161.048, and entitled, Inspection of Shipment of Animals or Animal Products, "[t]he commission may require testing, vaccination, or another epidemiologically sound procedure before or after animals are moved. An agent of the Commission is entitled to stop and inspect a shipment of animals or animal products being transported in this state in order to determine if the shipment originated from a quarantined area or herd; or determine if the shipment presents a danger to the public health or livestock industry through insect infestation or through a communicable or noncommunicable disease."

Pursuant to §161.005, and entitled, Commission Written Instruments, "[t]he Commission may authorize the executive director or another employee to sign written instruments on behalf of the commission. A written instrument, including a quarantine or written notice signed under that authority, has the same force and effect as if signed by the entire Commission."

Pursuant to §161.044, entitled Regulation of Livestock Movement from Stockyards or Railway Shipping Pens, "[t]he commission may regulate the movement of livestock out of stockyards or railway shipping pens and require treatment or certification of those animals as reasonably necessary to protect against communicable diseases".

Pursuant to §161.046, entitled Rules, "[t]he commission may adopt rules as necessary for the administration and enforcement of this chapter."

Pursuant to §161.049, entitled Dealer Records, "[t]he commission may require a livestock, exotic livestock, domestic fowl, or exotic fowl dealer to maintain records of all livestock, exotic livestock, domestic fowl, or exotic fowl bought and sold by the dealer."

Pursuant to §161.061, entitled Establishment, "[i]f the commission determines that a disease listed in Section 161.041 of this code or an agency of transmission of one of those diseases exists in a place in this state or among livestock, exotic livestock, domestic animals, domestic fowl, or exotic fowl, or that a place in this state or livestock, exotic livestock, domestic animals, domestic fowl, or exotic fowl are exposed to one of those diseases or an agency of transmission of one of those diseases."

Pursuant to §161.081, entitled Importation of Animals, "[t]he commission by rule may regulate the movement, including movement by a railroad company or other common carrier, of livestock, exotic livestock, domestic animals, domestic fowl, or exotic fowl into this state from another state, territory, or country."

Pursuant to §161.112, entitled Rules, "[t]he commission shall adopt rules relating to the movement of livestock, exotic livestock, and exotic fowl from livestock markets and shall require tests, immunization, and dipping of those livestock as necessary to protect against the spread of communicable diseases."

Pursuant to §161.113, entitled Testing or Treatment of Livestock, "[i]f the commission requires testing or vaccination under this subchapter, the testing or vaccination must be performed by an accredited veterinarian or qualified person authorized by the commission. The state may not be required to pay the cost of fees charged for the testing or vaccination. And if the commission requires the dipping of livestock under this subchapter, the livestock shall be submerged in a vat, sprayed, or treated in another sanitary manner prescribed by rule of the commission."

Pursuant to §161.114, entitled Inspection of Livestock "[a]n authorized inspector may examine livestock consigned to and delivered on the premises of a livestock market before the livestock are offered for sale. If the inspector considers it necessary, the inspector may have an animal tested or vaccinated. Any testing or vaccination must occur before the animal is removed from the livestock market."

No other statutes, articles or codes are affected by the proposal.

§51.9. Exotic Livestock and Fowl.

(a) Exotic Livestock. The following named species entering the State of Texas shall meet the specific requirements in paragraphs (1) - (4) of this subsection:

(1) Exotic cervidae--Negative [~~Originates from a Certified Free Herd or negative~~] to a brucellosis test within 30 days prior to entry if from the Brucellosis Designated Surveillance Area (DSA) located in the states of Idaho, Wyoming, and Montana or for any free ranging exotic cervidae trapped for movement. Tuberculosis test requirements see §51.10(c) of this chapter (relating to Cervidae). Susceptible species (i.e. elk) must meet the Chronic Wasting Disease requirements, see §51.10(a) and (b) of this title [~~chapter~~].

(2) Exotic Bovidae--Negative to a brucellosis test within 30 days prior to entry. Negative to a tuberculosis test within 60 days prior to entry.

(3) Camelidae--The executive director of the commission may require a brucellosis and tuberculosis test of any camelidae, from out of state, when there is epidemiological risk of exposure or infection to either disease. Entry may be denied based on the results of these tests or inspections.

(4) Exotic Swine--Tested negative to pseudorabies and brucellosis within 30 days prior to entry or originate from a brucellosis validated free and pseudorabies qualified free herd, in addition to an entry permit and a certificate of veterinary inspection.

(b) Exotic Fowl. Ratites entering the State of Texas shall meet the specific requirements listed in paragraphs (1) - (4) of this subsection:

(1) Each bird will be individually identified with either an RFID device, a permanently attached tag or an implanted electronic device (microchip). The identification will be shown on the certificate of veterinary inspection along with the location and name brand of the implanted electronic device. If an animal has more than one implanted microchip, then the location, microchip number, and name brand of each will be documented on the certificate of veterinary inspection. Birds or hatching eggs must originate from flocks that show no evidence of infectious disease and have had no history of Avian Influenza in the past six months. In addition, each bird must be tested and found to be serologically negative for Avian Influenza and Salmonella pullorum-typhoid from a sample collected within 30 days of shipment. A bird serologically positive for Avian Influenza may be admitted if a virus isolation test via cloacal swab conducted within 30 days of shipment is negative for Avian Influenza. The testing is to be performed in a state approved diagnostic laboratory in the state of origin. Sero-

logically positive birds admitted under this section must be held under quarantine on the premise of destination in Texas for virus isolation retest.

(2) Ratites destined for slaughter only may enter Texas accompanied by an entry permit and either an owner-shipper statement or health certificate without meeting the requirements of paragraph (1) of this subsection.

(3) All ratites originating within Texas and changing ownership or being offered for public sale or sold by private treaty within the state must be individually identified with an implanted electronic device, a tag or band.

(4) All identification must be maintained in the sale records for consignments to a public sale or in the records of the buyer and seller when the animals are sold at private treaty. These records must be maintained for a period of three years.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 18, 2018.

TRD-201805500
Larissa Scmidt
Chief of Staff
Texas Animal Health Commission
Earliest possible date of adoption: February 3, 2019
For further information, please call: (512) 719-0722

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TITLE 22. EXAMINING BOARDS

PART 15. TEXAS STATE BOARD OF PHARMACY

CHAPTER 281. ADMINISTRATIVE PRACTICE AND PROCEDURES

SUBCHAPTER C. DISCIPLINARY GUIDELINES

22 TAC §281.68

The Texas State Board of Pharmacy proposes amendments to §281.68, concerning Remedial Plan. The amendments, if adopted, clarify that the Board shall remove all records of a completed remedial plan at the end of the fiscal year of the fifth anniversary of the date the board entered the remedial plan in accordance with section 565.060 of the Pharmacy Act.

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to provide consistency between state law and Board rules regarding the retention of records relating to completed remedial plans. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendment will be in effect, Ms. Benz has determined the following:

(1) The proposed rule does not create or eliminate a government program;

(2) Implementation of the proposed rule does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed rule does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed rule does not require an increase or decrease in fees paid to the agency;

(5) The proposed rule does not create a new regulation;

(6) The proposed rule does not limit or expand an existing regulation;

(7) The proposed rule does not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed rule does not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Assistant General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., February 3, 2019.

The amendments are proposed under §§551.002, 554.051, and 562.1011 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§281.68. Remedial Plan.

(a) The board may issue a remedial plan by agreement with the respondent to resolve the investigation of a complaint relating to the Act unless the complaint involves:

(1) a death;

(2) a hospitalization;

(3) the commission of a felony;

(4) the unlicensed practice of a licensee or registrant;

(5) audit shortages;

(6) diversion of controlled substances;

(7) impairment by chemical abuse or mental or physical illness of a licensee or registrant;

(8) unauthorized dispensing of a prescription drug;

(9) gross immorality as defined by the board;

(10) engaging in fraud, deceit, or misrepresentation as defined by board rule;

(11) disciplinary action by another regulatory board of this state or another state; or

(12) any other matter determined by the board.

(b) The board shall not impose a remedial plan if the appropriate resolution of the complaint involves a restriction on the manner in which a license holder practices pharmacy.

(c) The board may not issue a remedial plan to resolve a complaint against a license holder if the license holder has entered into a remedial plan with the board in the preceding 24 months for the resolution of a different complaint relating to this subtitle.

(d) If a license holder complies with and successfully completes the terms of a remedial plan, the board shall remove all records of the remedial plan from the board's records at the end of the fiscal year in which the fifth anniversary of the date the board issued the terms of the remedial plan occurs in accordance with §565.060 of the Act [~~on the fifth anniversary of the date the board issued the terms of the remedial plan~~].

(e) The board may assess a fee against a license holder participating in a remedial plan in the [~~an~~] amount of $1,000 to recover the costs of administering the plan.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 19, 2018.

TRD-201805529
Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: February 3, 2019
For further information, please call: (512) 305-8010

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CHAPTER 283. LICENSING REQUIREMENTS FOR PHARMACISTS

22 TAC §283.12

The Texas State Board of Pharmacy proposes amendments to §283.12, concerning Licenses for Military Service Members, Military Veterans, and Military Spouses. The amendments, if adopted, allow a military service member, military veteran, or military spouse to place his or her pharmacist license on inactive status while not practicing pharmacy in Texas without paying a fee.

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to decrease the financial burden of placing a pharmacist license on inactive status for military service members, military veterans, or military spouses who move out of state or temporarily stop practicing pharmacy in Texas. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendment will be in effect, Ms. Benz has determined the following:

(1) The proposed rule does not create or eliminate a government program;

(2) Implementation of the proposed rule does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed rule does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed rule does require a decrease in fees paid to the agency;

(5) The proposed rule does not create a new regulation;

(6) The proposed rule does limit an existing regulation by lowering the number of licensees required to pay a certain fee;

(7) The proposed rule does not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed rule does not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Assistant General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., February 3, 2019.

The amendments are proposed under §§551.002, 554.051, and 562.1011 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§283.12. Licenses for Military Service Members, Military Veterans, and Military Spouses.

(a) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Active duty--Current full-time military service in the armed forces of the United States or active duty military service as a member of the Texas military forces, or similar military service of another state.

(2) Armed forces of the United States--The army, navy, air force, coast guard, or marine corps of the United States or a reserve unit of one of those branches of the armed forces.

(3) Military service member--A person who is on active duty.

(4) Military spouse--A person who is married to a military service member.

(5) Military veteran--A person who has served on active duty and who was discharged or released from active duty.

(b) Alternative licensing procedure. For the purpose of §55.004, Occupations Code, an applicant for a pharmacist

[~~pharmacist's~~] license who is a military service member, military veteran, or military spouse may complete the following alternative procedures for licensing as a pharmacist.

(1) Requirements for licensing by reciprocity. An applicant for licensing by reciprocity who meets all of the following requirements may be granted a temporary license as specified in this subsection prior to completing the NABP application for pharmacist license by reciprocity, and taking and passing the Texas Pharmacy Jurisprudence Examination. The applicant shall:

(A) complete the Texas application for pharmacist license by reciprocity that includes the following:

(i) name;

(ii) addresses, phone numbers, date of birth, and social security number; and

(iii) any other information requested on the application;

(B) meet the educational and age requirements as set forth in §283.3 of this title (relating to Educational and Age Requirements);

(C) present to the board proof of initial licensing by examination and proof that any current licenses and any other licenses granted to the applicant by any other state have not been suspended, revoked, canceled, surrendered, or otherwise restricted for any reason;

(D) meet all requirements necessary for the board to access the criminal history records information, including submitting fingerprint information, and such criminal history check does not reveal any disposition for a crime specified in §281.64 of this title (relating to Sanctions for Criminal Offenses) indicating [~~indicates~~] a sanction of denial, revocation, or suspension; and

(E) be exempt from the application and examination fees paid to the board set forth in §283.9(a)(2)(A) and (b) of this title (relating to Fee Requirements for Licensure by Examination, Score Transfer and Reciprocity); and

(F) provide documentation of eligibility, including [~~to include~~]:

(i) military identification indicating that the applicant is a military service member, military veteran, or military dependent, if a military spouse; and

(ii) marriage certificate, if a military spouse.

(2) Requirements for an applicant whose Texas pharmacist [~~pharmacist's~~] license has expired. An applicant whose Texas pharmacist [~~pharmacist's~~] license has expired within five years preceding the application date:

(A) shall complete the Texas application for licensing that includes the following:

(i) name;

(ii) addresses, phone numbers, date of birth, and social security number; and

(iii) any other information requested on the application;

(B) shall provide documentation of eligibility, including [~~to include~~]:

(i) military identification indicating that the applicant is a military service member, military veteran, or military dependent, if a military spouse; and

(ii) marriage certificate, if a military spouse;

(C) shall pay the renewal fee specified in §295.5 of this title (relating to Pharmacist License or Renewal Fees); however, the applicant shall be exempt from the fees specified in §295.7(3) of this title (relating to Pharmacist License Renewal).

(D) shall complete approved continuing education requirements according to the following schedule:

(i) if the Texas pharmacist license has been expired for more than one year but less than two years, the applicant shall complete 15 contact hours of approved continuing education;

(ii) if the Texas pharmacist license has been expired for more than two years but less than three years, the applicant shall complete 30 contact hours of approved continuing education; or

(iii) if the Texas pharmacist license has been expired for more than three years but less than five years, the applicant shall complete 45 contact hours of approved continuing education; and

(E) is not required to take the Texas Pharmacy Jurisprudence Examination.

(3) A temporary license issued under this section is valid for no more than six months and may be extended, if disciplinary action is pending, or upon request, as otherwise determined reasonably necessary by the executive director of the board.

(4) A temporary license issued under this section expires within six months of issuance if the individual fails to pass the Texas Pharmacy Jurisprudence Examination within six months or fails to take the Texas Pharmacy Jurisprudence Examination within six months.

(5) An individual may not serve as pharmacist-in-charge of a pharmacy with a temporary license issued under this subsection.

(c) Expedited licensing procedure. For the purpose of §55.005, Occupations Code, an applicant for a pharmacist license who is a military service member, military veteran, or military spouse and who holds a current license as a pharmacist issued by another state may complete the following expedited procedures for licensing as a pharmacist. The applicant shall:

(1) meet the educational and age requirements specified in §283.3 of this title (relating to Educational and Age Requirements);

(2) meet all requirements necessary in order for the board to access the criminal history record information, including submitting fingerprint information and being responsible for all associated costs;

(3) complete the Texas and NABP applications for reciprocity. Any fraudulent statement made in the application for reciprocity is grounds for denial of the application. If [~~, if~~] such application is granted, any fraudulent statement is grounds for suspension, revocation, and/or cancellation of any license so granted by the board. The Texas application includes the following information:

(A) name;

(B) addresses, phone numbers, date of birth, and social security number; and

(C) any other information requested on the application.

(4) [~~shall~~] present to the board proof of initial licensing by examination and proof that their current license and any other license or licenses granted to the applicant by any other state have not been suspended, revoked, canceled, surrendered, or otherwise restricted for any reason;

(5) [~~shall~~] pass the Texas Pharmacy Jurisprudence Examination with a minimum grade of 75. (The passing grade may be used for the purpose of licensure by reciprocity for a period of two years from the date of passing the examination.) Should the applicant fail to achieve a minimum grade of 75 on the Texas Pharmacy Jurisprudence Examination, such applicant, in order to be licensed, shall retake the Texas Pharmacy Jurisprudence Examination as specified in §283.11 of this title (relating to Examination Retake Requirements) until such time as a minimum grade of 75 is achieved; and

(6) [~~shall~~] be exempt from the application and examination fees paid to the board set forth in §283.9(a)(2)(A) and (b).

(d) License renewal. As specified in §55.003, Occupations Code, a military service member who holds a pharmacist license is entitled to two years of additional time to complete any requirements related to the renewal of the military service member's license as follows:

(1) A military service member who fails to renew their pharmacist license in a timely manner because the individual was serving as a military service member shall submit to the board:

(A) name, address, and license number of the pharmacist;

(B) military identification indicating that the individual is a military service member; and

(C) a statement requesting up to two years of additional time to complete the renewal.

(2) A military service member specified in paragraph (1) of this subsection shall be exempt from fees specified in §295.7(3) of this title (relating to Pharmacist License Renewal).

(3) A military service member specified in paragraph (1) of this subsection is entitled to two additional years of time to complete the continuing education requirements specified in §295.8 [~~§295.9~~] of this title (relating to Continuing Education Requirements).

(e) Inactive status. The holder of a pharmacist license who is a military service member, a military veteran, or a military spouse who holds a pharmacist license and who is not engaged in the practice of pharmacy in this state may place the license on inactive status as specified in §295.9 of this title (relating to Inactive License). The inactive license holder:

(1) shall provide documentation to include:

(A) military identification indicating that the pharmacist is a military service member, military veteran, or military dependent, if a military spouse; and

(B) marriage certificate, if a military spouse;

(2) shall be exempt from the fees specified in §295.9(a)(1)(C) and §295.9(a)(2)(C) of this title;

(3) shall not practice pharmacy in this state; and

(4) may reactivate the license as specified in §295.9 of this title (relating to Inactive license).

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 19, 2018.

TRD-201805530

Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: February 3, 2019
For further information, please call: (512) 305-8010

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CHAPTER 291. PHARMACIES
SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)

22 TAC §291.31

The Texas State Board of Pharmacy proposes amendments to §291.31, concerning Definitions. The amendments, if adopted, update the definitions of an automated counting device and automated pharmacy dispensing system, and correct grammatical errors.

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to provide clearer regulatory language for Class A pharmacies utilizing automated counting and dispensing systems. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendment will be in effect, Ms. Benz has determined the following:

(1) The proposed rule does not create or eliminate a government program;

(2) Implementation of the proposed rule does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed rule does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed rule does not require an increase or decrease in fees paid to the agency;

(5) The proposed rule does not create a new regulation;

(6) The proposed rule does not limit or expand an existing regulation;

(7) The proposed rule does not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed rule does not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Assistant General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., February 3, 2019.

The amendments are proposed under §§551.002, 554.051, and 562.1011 of the Texas Pharmacy Act (Chapters 551 - 569, Texas

Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.31. Definitions.

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Accurately as prescribed--Dispensing, delivering, and/or distributing a prescription drug order:

(A) to the correct patient (or agent of the patient) for whom the drug or device was prescribed;

(B) with the correct drug in the correct strength, quantity, and dosage form ordered by the practitioner; and

(C) with correct labeling (including directions for use) as ordered by the practitioner. Provided, however, that nothing herein shall prohibit pharmacist substitution if substitution is conducted in strict accordance with applicable laws and rules, including Chapter 562 of the Texas Pharmacy Act.

(2) Act--The Texas Pharmacy Act, Chapters 551 - 569 [~~551 - 566 and 568 - 569~~], Occupations Code, as amended.

(3) Advanced practice registered nurse--A registered nurse licensed by the Texas Board of Nursing to practice as an advanced practice registered nurse on the basis of completion of an advanced education program. The term includes nurse practitioner, nurse midwife, nurse anesthetist, and clinical nurse specialist. The term is synonymous with advanced nurse practitioner and advanced practice nurse.

(4) Automated checking device--A device that confirms that the correct drug and strength has been labeled with the correct label for the correct patient prior to delivery of the drug to the patient.

(5) Automated [~~compounding or~~] counting device--An automated device that is loaded with bulk drugs and[~~compounds, measures,~~] counts[~~,~~] and/or packages (i.e., fills a vial or other container) a specified quantity of dosage units of a designated drug product.

(6) Automated pharmacy dispensing system [~~systems~~]--A [~~mechanical~~] system that automatically performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, and labeling for[~~,~~] dispensing and delivery[~~, and distribution~~] of medications, and that [~~which~~] collects, controls, and maintains all transaction information. "Automated pharmacy dispensing system [~~systems~~]" does not mean "Automated compounding or counting device [~~devices~~]" or "Automated medication supply device [~~devices~~]."

(7) Beyond use date--The date beyond which a product should not be used.

(8) Board--The Texas State Board of Pharmacy.

(9) Confidential record--Any health-related record that contains information that identifies an individual and that is maintained by a pharmacy or pharmacist, such as a patient medication record, prescription drug order, or medication order.

(10) Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I - V or Penalty Groups 1 - 4[~~1-4~~] of the Texas Controlled Substances Act, as amended (Chapter 481, Health and Safety Code), or a drug, immediate precursor, or other substance included in Schedules I, II, III, IV, or V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).

(11) Dangerous drug--A drug or device that:

(A) is not included in Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended, [~~Group 1, 2, 3, or 4,~~] (Chapter 481, Health and Safety Code), and is unsafe for self-medication; or

(B) bears or is required to bear the legend:

(i) "Caution: federal law prohibits dispensing without prescription" or "Rx only" or another legend that complies with federal law; or

(ii) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian."

(12) Data communication device--An electronic device that receives electronic information from one source and transmits or routes it to another (e.g., bridge, router, switch or gateway).

(13) Deliver or delivery--The actual, constructive, or attempted transfer of a prescription drug or device or controlled substance from one person to another, whether or not for a consideration.

(14) Designated agent--

(A) a licensed nurse, physician assistant, pharmacist, or other individual designated by a practitioner to communicate prescription drug orders to a pharmacist;

(B) a licensed nurse, physician assistant, or pharmacist employed in a health care facility to whom the practitioner communicates a prescription drug order;

(C) an advanced practice registered nurse or physician assistant authorized by a practitioner to prescribe or order drugs or devices under Chapter 157 of the Medical Practice Act (Subtitle B, Occupations Code); or

(D) a person who is a licensed vocational nurse or has an education equivalent to or greater than that required for a licensed vocational nurse designated by the practitioner to communicate prescriptions for an advanced practice registered nurse or physician assistant authorized by the practitioner to sign prescription drug orders under Chapter 157 of the Medical Practice Act (Subtitle B, Occupations Code).

(15) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(16) Dispensing error--An action committed by a pharmacist or other pharmacy personnel that causes the patient or patient's agent to take possession of a dispensed prescription drug and an individual subsequently discovers that the patient has received an incorrect drug product, which includes incorrect strength, incorrect dosage form, and/or incorrect directions for use.

(17) Dispensing pharmacist--The pharmacist responsible for the final check of the dispensed prescription before delivery to the patient.

(18) Distribute--The delivery of a prescription drug or device other than by administering or dispensing.

(19) Downtime--Period of time during which a data processing system is not operable.

(20) Drug regimen review--An evaluation of prescription drug orders and patient medication records for:

(A) known allergies;

(B) rational therapy-contraindications;

(C) reasonable dose and route of administration;

(D) reasonable directions for use;

(E) duplication of therapy;

(F) drug-drug interactions;

(G) drug-food interactions;

(H) drug-disease interactions;

(I) adverse drug reactions; and

(J) proper utilization, including overutilization or underutilization.

(21) Electronic prescription drug order--A prescription drug order that is generated on an electronic application and transmitted as an electronic data file.

(22) Electronic signature--A unique security code or other identifier which specifically identifies the person entering information into a data processing system. A facility which utilizes electronic signatures must:

(A) maintain a permanent list of the unique security codes assigned to persons authorized to use the data processing system; and

(B) have an ongoing security program which is capable of identifying misuse and/or unauthorized use of electronic signatures.

(23) Electronic verification process--an electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system that accurately verifies that medication has been properly dispensed and labeled by, or loaded into, an automated pharmacy dispensing system.

(24) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or, if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.

(25) Hard copy--A physical document that is readable without the use of a special device.

(26) Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of 105 degrees F (41 degrees C).

(27) Medical Practice Act--The Texas Medical Practice Act, Subtitle B, Occupations Code, as amended.

(28) Medication order--A written order from a practitioner or a verbal order from a practitioner or his authorized agent for administration of a drug or device.

(29) New prescription drug order--A prescription drug order that has not been dispensed to the patient in the same strength and dosage form by this pharmacy within the last year.

(30) Original prescription--The:

(A) original written prescription drug order; or

(B) original verbal or electronic prescription drug order reduced to writing either manually or electronically by the pharmacist.

(31) Part-time pharmacist--A pharmacist who works less than full-time.

(32) Patient med-pak--A package prepared by a pharmacist for a specific patient comprised of a series of containers and containing two or more prescribed solid oral dosage forms. The patient med-pak is so designed or each container is so labeled as to indicate the day and time, or period of time, that the contents within each container are to be taken.

(33) Patient counseling--Communication by the pharmacist of information to the patient or patient's agent in order to improve therapy by ensuring proper use of drugs and devices.

(34) Pharmaceutical care--The provision of drug therapy and other pharmaceutical services intended to assist in the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.

(35) Pharmacist-in-charge--The pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

(36) Pharmacy technician--An individual who is registered with the board as a pharmacy technician and whose responsibility in a pharmacy is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible to a pharmacist.

(37) Pharmacy technician trainee--An individual who is registered with the board as a pharmacy technician trainee and is authorized to participate in a pharmacy's technician training program.

(38) Physician assistant--A physician assistant recognized by the Texas Medical Board as having the specialized education and training required under Subtitle B, Chapter 157, Occupations Code, and issued an identification number by the Texas Medical Board.

(39) Practitioner--

(A) a person licensed or registered to prescribe, distribute, administer, or dispense a prescription drug or device in the course of professional practice in this state, including a physician, dentist, podiatrist, or veterinarian but excluding a person licensed under this Act;

(B) a person licensed by another state, Canada, or the United Mexican States in a health field in which, under the law of this state, a license holder in this state may legally prescribe a dangerous drug;

(C) a person practicing in another state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a current federal Drug Enforcement Administration registration number and who may legally prescribe a Schedule II, III, IV, or V controlled substance, as specified under Chapter 481, Health and Safety Code, in that other state; or

(D) an advanced practice registered nurse or physician assistant to whom a physician has delegated the authority to prescribe or order drugs or devices under Chapter 157 of the Medical Practice Act (Subtitle B, Occupations Code) or, for the purpose of this subchapter, a pharmacist who practices in a hospital, hospital-based clinic, or an academic health care institution and to whom a physician has delegated the authority to sign a prescription for a dangerous drug under §157.101, Occupations Code.

(40) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original commercial container into a prescription container, unit-dose packaging, or multi-compartment container for dispensing by a pharmacist to the ul-

timate consumer, including dispensing through the use of an automated pharmacy dispensing system or automated checking device.

(41) Prescription department--The area of a pharmacy that contains prescription drugs.

(42) Prescription drug--

(A) a substance for which federal or state law requires a prescription before the substance may be legally dispensed to the public;

(B) a drug or device that under federal law is required, before being dispensed or delivered, to be labeled with the statement:

(i) "Caution: federal law prohibits dispensing without prescription" or "Rx only" or another legend that complies with federal law; or

(ii) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian"; or

(C) a drug or device that is required by federal or state statute or regulation to be dispensed on prescription or that is restricted to use by a practitioner only.

(43) Prescription drug order--

(A) a written order from a practitioner or a verbal order from a practitioner or his authorized agent to a pharmacist for a drug or device to be dispensed; or

(B) a written order or a verbal order pursuant to Subtitle B, Chapter 157, Occupations Code.

(44) Prospective drug use review--A review of the patient's drug therapy and prescription drug order or medication order prior to dispensing or distributing the drug.

(45) State--One of the 50 United States of America, a U.S. territory, or the District of Columbia.

(46) Texas Controlled Substances Act--The Texas Controlled Substances Act, Health and Safety Code, Chapter 481, as amended.

(47) Written protocol--A physician's order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Texas Medical Board under the Texas Medical Practice Act.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 19, 2018.

TRD-201805531
Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: February 3, 2019
For further information, please call: (512) 305-8010

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22 TAC §291.33

The Texas State Board of Pharmacy proposes amendments to §291.33, concerning Operational Standards. The amendments, if adopted, clarify the pharmacist's patient counseling duties by expressly prohibiting a pharmacy's computer system from asking questions of the patient intended to screen and/or limit interaction with the pharmacist, and update the requirements for the use of automated devices and systems in Class A pharmacies to be consistent with the proposed updated definitions in §291.31 and changes in technology, remove the provisions relating to automated storage and distribution devices from this section, and correct grammatical errors.

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to provide the public with better access to prescription drug information by removing barriers between the patient and the pharmacist and to provide clearer regulatory language for Class A pharmacies utilizing automated pharmacy devices or systems and to provide the requirements for the use of automated storage and distribution devices in a more appropriate section of the rules in light of technological advances. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendment will be in effect, Ms. Benz has determined the following:

(1) The proposed rule does not create or eliminate a government program;

(2) Implementation of the proposed rule does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed rule does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed rule does not require an increase or decrease in fees paid to the agency;

(5) The proposed rule does not create a new regulation;

(6) The proposed rule does expand an existing regulation by expressly prohibiting a type of patient screening and also limits an existing regulation by removing the provisions relating to automated storage and distribution devices from this section; however, proposed amendments to §291.121 would include the addition of provisions relating to automated storage and distribution devices to that section;

(7) The proposed rule does not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed rule does not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Assistant General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., February 3, 2019.

The amendments are proposed under §§551.002, 554.051, and 562.1011 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control

and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551- 569, Texas Occupations Code.

§291.33. Operational Standards.

(a) - (b) (No change.)

(c) Prescription dispensing and delivery.

(1) Patient counseling and provision of drug information.

(A) To optimize drug therapy, a pharmacist shall communicate to the patient or the patient's agent[,] information about the prescription drug or device which in the exercise of the pharmacist's professional judgment the pharmacist deems significant, such as the following:

(i) name and description of the drug or device;

(ii) dosage form, dosage, route of administration, and duration of drug therapy;

(iii) special directions and precautions for preparation, administration, and use by the patient;

(iv) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(v) techniques for self-monitoring of drug therapy;

(vi) proper storage;

(vii) refill information; and

(viii) action to be taken in the event of a missed dose.

(B) Such communication shall be:

(i) provided to new and existing patients of a pharmacy with each new prescription drug order. A new prescription drug order is one that has not been dispensed by the pharmacy to the patient in the same dosage and strength within the last year;

(ii) provided for any prescription drug order dispensed by the pharmacy on the request of the patient or patient's agent;

(iii) communicated orally in person unless the patient or patient's agent is not at the pharmacy or a specific communication barrier prohibits such oral communication;

(iv) documented by recording the initials or identification code of the pharmacist providing the counseling in the prescription dispensing record as follows:

(I) on the original hard-copy prescription, provided the counseling pharmacist clearly records his or her initials on the prescription for the purpose of identifying who provided the counseling;

(II) in the pharmacy's data processing system;

(III) in an electronic logbook; or

(IV) in a hard-copy log; and

(v) reinforced with written information relevant to the prescription and provided to the patient or patient's agent. The following is applicable concerning this written information:[.]

(I) Written information must be in plain language designed for the patient and printed in an easily readable font comparable to but no smaller than ten-point Times Roman. This information may be provided to the patient in an electronic format, such as by e-mail, if the patient or patient's agent requests the information in an electronic format and the pharmacy documents the request.

(II) When a compounded preparation is dispensed, information shall be provided for the major active ingredient(s), if available.

(III) For new drug entities, if no written information is initially available, the pharmacist is not required to provide information until such information is available, provided:

(-a-) the pharmacist informs the patient or the patient's agent that the product is a new drug entity and written information is not available;

(-b-) the pharmacist documents the fact that no written information was provided; and

(-c-) if the prescription is refilled after written information is available, such information is provided to the patient or patient's agent.

(IV) The written information accompanying the prescription or the prescription label shall contain the statement "Do not flush unused medications or pour down a sink or drain." A drug product on a list developed by the Federal Food and Drug Administration of medicines recommended for disposal by flushing is not required to bear this statement.

(C) Only a pharmacist may verbally provide drug information to a patient or patient's agent and answer questions concerning prescription drugs. Non-pharmacist personnel and/or the pharmacy's computer system may not ask questions of a patient or patient's agent which are intended to screen and/or limit interaction with the pharmacist.

(D) Nothing in this subparagraph shall be construed as requiring a pharmacist to provide consultation when a patient or patient's agent refuses such consultation. The pharmacist shall document such refusal for consultation.

(E) In addition to the requirements of subparagraphs (A) - (D) of this paragraph, if a prescription drug order is delivered to the patient at the pharmacy, the following is applicable:[.]

(i) So that a patient will have access to information concerning his or her prescription, a prescription may not be delivered to a patient unless a pharmacist is in the pharmacy, except as provided in subsection (b)(3) of this section.

(ii) Any prescription delivered to a patient when a pharmacist is not in the pharmacy must meet the requirements described in subparagraph (F) of this paragraph.

(F) In addition to the requirements of subparagraphs (A) - (D) of this paragraph, if a prescription drug order is delivered to the patient or his or her agent at the patient's residence or other designated location, the following is applicable:[.]

(i) The information as specified in subparagraph (A) of this paragraph shall be delivered with the dispensed prescription in writing.

(ii) If prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacy shall provide a toll-free telephone line which is answered during normal business hours to enable communication between the patient and a pharmacist.

(iii) The pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container in both English and Spanish the local and, if applicable, toll-free

telephone number of the pharmacy and the statement: "Written information about this prescription has been provided for you. Please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at (insert the pharmacy's local and toll-free telephone numbers)."

(iv) The pharmacy shall maintain and use adequate storage or shipment containers and use shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process.

(v) The pharmacy shall use a delivery system[,] which is designed to assure that the drugs are delivered to the appropriate patient.

(G) The provisions of this paragraph do not apply to patients in facilities where drugs are administered to patients by a person required to do so by the laws of the state (i.e., nursing homes).

(2) Pharmaceutical care services.

(A) Drug regimen review.

(i) For the purpose of promoting therapeutic appropriateness, a pharmacist shall, prior to or at the time of dispensing a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant:

(I) known allergies;

(II) rational therapy-contraindications;

(III) reasonable dose and route of administration;

(IV) reasonable directions for use;

(V) duplication of therapy;

(VI) drug-drug interactions;

(VII) drug-food interactions;

(VIII) drug-disease interactions;

(IX) adverse drug reactions; and

(X) proper utilization, including overutilization or underutilization.

(ii) Upon identifying any clinically significant conditions, situations, or items listed in clause (i) of this subparagraph, the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner. The pharmacist shall document such occurrences as specified in subparagraph (C) of this paragraph.

(iii) The drug regimen review may be conducted by remotely accessing the pharmacy's electronic database from outside the pharmacy by:

(I) an individual Texas licensed pharmacist employee of the pharmacy provided the pharmacy establishes controls to protect the privacy of the patient and the security of confidential records; or

(II) a pharmacist employed by a Class E pharmacy provided the pharmacies have entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations.

(iv) Prior to dispensing, any questions regarding a prescription drug order must be resolved with the prescriber and written documentation of these discussions made and maintained as specified in subparagraph (C) of this paragraph.

(B) Other pharmaceutical care services which may be provided by pharmacists include, but are not limited to, the following:

(i) managing drug therapy as delegated by a practitioner as allowed under the provisions of the Medical Practice Act;

(ii) administering immunizations and vaccinations under written protocol of a physician;

(iii) managing patient compliance programs;

(iv) providing preventative health care services; and

(v) providing case management of patients who are being treated with high-risk or high-cost drugs, or who are considered "high risk" due to their age, medical condition, family history, or related concern.

(C) Documentation of consultation. When a pharmacist consults a prescriber as described in subparagraph (A) of this paragraph the pharmacist shall document on the prescription or in the pharmacy's data processing system associated with the prescription such occurrences and shall include the following information:

(i) date the prescriber was consulted;

(ii) name of the person communicating the prescriber's instructions;

(iii) any applicable information pertaining to the consultation; and

(iv) initials or identification code of the pharmacist performing the consultation clearly recorded for the purpose of identifying the pharmacist who performed the consultation.

(3) Substitution of generically equivalent drugs or interchangeable biological products. A pharmacist may dispense a generically equivalent drug or interchangeable biological product and shall comply with the provisions of §309.3 of this title (relating to Substitution Requirements).

(4) Substitution of dosage form.

(A) As specified in §562.012 of the Act, a pharmacist may dispense a dosage form of a drug product different from that prescribed, such as a tablet instead of a capsule or liquid instead of tablets, provided:

(i) the patient consents to the dosage form substitution; and

(ii) the dosage form so dispensed:

(I) contains the identical amount of the active ingredients as the dosage prescribed for the patient;

(II) is not an enteric-coated or time release product; and

(III) does not alter desired clinical outcomes.[;]

(B) Substitution of dosage form may not include the substitution of a product that has been compounded by the pharmacist unless the pharmacist contacts the practitioner prior to dispensing and obtains permission to dispense the compounded product.

(5) Therapeutic Drug Interchange. A switch to a drug providing a similar therapeutic response to the one prescribed shall not be made without prior approval of the prescribing practitioner. This para-

graph does not apply to generic substitution. For generic substitution, see the requirements of paragraph (3) of this subsection.

(A) The patient shall be notified of the therapeutic drug interchange prior to, or upon delivery, of the dispensed prescription to the patient. Such notification shall include:

(i) a description of the change;

(ii) the reason for the change;

(iii) whom to notify with questions concerning the change; and

(iv) instructions for return of the drug if not wanted by the patient.

(B) The pharmacy shall maintain documentation of patient notification of therapeutic drug interchange which shall include:

(i) the date of the notification;

(ii) the method of notification;

(iii) a description of the change; and

(iv) the reason for the change.

(C) The provisions of this paragraph do not apply to prescriptions for patients in facilities where drugs are administered to patients by a person required to do so by the laws of this state if the practitioner issuing the prescription has agreed to use of a formulary that includes a listing of therapeutic interchanges that the practitioner has agreed to allow. The pharmacy must maintain a copy of the formulary including a list of the practitioners that have agreed to the formulary and the signature of these practitioners.

(6) Prescription containers.

(A) A drug dispensed pursuant to a prescription drug order shall be dispensed in a child-resistant container unless:

(i) the patient or the practitioner requests the prescription not be dispensed in a child-resistant container; or

(ii) the product is exempted from requirements of the Poison Prevention Packaging Act of 1970.

(B) A drug dispensed pursuant to a prescription drug order shall be dispensed in an appropriate container as specified on the manufacturer's container.

(C) Prescription containers or closures shall not be re-used. However, if a patient or patient's agent has difficulty reading or understanding a prescription label, a prescription container may be reused provided:

(i) the container is designed to provide audio-recorded information about the proper use of the prescription medication;

(ii) the container is reused for the same patient;

(iii) the container is cleaned; and

(iv) a new safety closure is used each time the prescription container is reused.

(7) Labeling.

(A) At the time of delivery of the drug, the dispensing container shall bear a label in plain language and printed in an easily readable font size, unless otherwise specified, with at least the following information:

(i) name, address and phone number of the pharmacy;

(ii) unique identification number of the prescription that is printed in an easily readable font size comparable to but no smaller than ten-point Times Roman;

(iii) date the prescription is dispensed;

(iv) initials or an identification code of the dispensing pharmacist;

(v) name of the prescribing practitioner;

(vi) if the prescription was signed by a pharmacist, the name of the pharmacist who signed the prescription for a dangerous drug under delegated authority of a physician as specified in Subtitle B, Chapter 157, Occupations Code;

(vii) name of the patient or if such drug was prescribed for an animal, the species of the animal and the name of the owner that is printed in an easily readable font size comparable to but no smaller than ten-point Times Roman. The name of the patient's partner or family member is not required to be on the label of a drug prescribed for a partner for a sexually transmitted disease or for a patient's family members if the patient has an illness determined by the Centers for Disease Control and Prevention, the World Health Organization, or the Governor's office to be pandemic;

(viii) instructions for use that are [~~is~~] printed in an easily readable font comparable to but no smaller than ten-point Times Roman;

(ix) quantity dispensed;

(x) appropriate ancillary instructions such as storage instructions or cautionary statements such as warnings of potential harmful effects of combining the drug product with any product containing alcohol;

(xi) if the prescription is for a Schedule [~~Schedules~~] II - IV controlled substance, the statement "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed";

(xii) if the pharmacist has selected a generically equivalent drug or interchangeable biological product pursuant to the provisions of the Act, Chapter 562, the statement "Substituted for Brand Prescribed" or "Substituted for 'Brand Name'" where "Brand Name" is the actual name of the brand name product prescribed;

(xiii) the name and strength of the actual drug or biological product dispensed that is printed in an easily readable size comparable to but no smaller than ten-point Times Roman, unless otherwise directed by the prescribing practitioner;

(I) The name shall be either:

(-a-) the brand name; or

(-b-) if no brand name, then the generic drug or interchangeable biological product name and name of the manufacturer or distributor of such generic drug or interchangeable biological product. (The name of the manufacturer or distributor may be reduced to an abbreviation or initials, provided the abbreviation or initials are sufficient to identify the manufacturer or distributor. For combination drug products or non-sterile compounded drug preparations having no brand name, the principal active ingredients shall be indicated on the label.)

(II) Except as provided in clause (xii) of this subparagraph, the brand name of the prescribed drug or biological product

shall not appear on the prescription container label unless it is the drug product actually dispensed.

(xiv) if the drug is dispensed in a container other than the manufacturer's original container, the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication; and

(xv) either on the prescription label or the written information accompanying the prescription, the statement "Do not flush unused medications or pour down a sink or drain." A drug product on a list developed by the Federal Food and Drug Administration of medicines recommended for disposal by flushing is not required to bear this statement.

(B) If the prescription label required in subparagraph (A) of this paragraph is printed in a type size smaller than ten-point Times Roman, the pharmacy shall provide the patient written information containing the information as specified in subparagraph (A) of this paragraph in an easily readable font comparable to but no smaller than ten-point Times Roman.

(C) The label is not required to include the initials or identification code of the dispensing pharmacist as specified in subparagraph (A) of this paragraph if the identity of the dispensing pharmacist is recorded in the pharmacy's data processing system. The record of the identity of the dispensing pharmacist shall not be altered in the pharmacy's data processing system.

(D) The dispensing container is not required to bear the label as specified in subparagraph (A) of this paragraph if:

(i) the drug is prescribed for administration to an ultimate user who is institutionalized in a licensed health care institution (e.g., nursing home, hospice, hospital);

(ii) no more than a 90-day supply is dispensed at one time;

(iii) the drug is not in the possession of the ultimate user prior to administration;

(iv) the pharmacist-in-charge has determined that the institution:

(I) maintains medication administration records which include adequate directions for use for the drug(s) prescribed;

(II) maintains records of ordering, receipt, and administration of the drug(s); and

(III) provides for appropriate safeguards for the control and storage of the drug(s); and

(v) the dispensing container bears a label that adequately:

(I) identifies the:

(-a-) pharmacy by name and address;

(-b-) unique identification number of the prescription;

(-c-) name and strength of the drug dispensed;

(-d-) name of the patient; and

(-e-) name of the prescribing practitioner or, if applicable, the name of the pharmacist who signed the prescription drug order;

(II) if the drug is dispensed in a container other than the manufacturer's original container, specifies the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication; and

(III) sets forth the directions for use and cautionary statements, if any, contained on the prescription drug order or required by law.

(8) Returning Undelivered Medication to Stock.

(A) As specified in §431.021(w), Health and Safety Code, a pharmacist may not accept an unused prescription or drug, in whole or in part, for the purpose of resale or re-dispensing to any person after the prescription or drug has been originally dispensed[,] or sold, except as provided in §291.8 of this title (relating to Return of Prescription Drugs). Prescriptions that have not been picked up by or delivered to the patient or patient's agent may be returned to the pharmacy's stock for dispensing.

(B) A pharmacist shall evaluate the quality and safety of the prescriptions to be returned to stock.

(C) Prescriptions returned to stock for dispensing shall not be mixed within the manufacturer's container.

(D) Prescriptions returned to stock for dispensing should be used as soon as possible and stored in the dispensing container. The expiration date of the medication shall be the lesser of one year from the dispensing date on the prescription label or the manufacturer's expiration date if dispensed in the manufacturer's original container.

(E) At the time of dispensing, the prescription medication shall be placed in a new prescription container and not dispensed in the previously labeled container unless the label can be completely removed. However, if the medication is in the manufacturer's original container, the pharmacy label must be removed so that no confidential patient information is released.

(d) - (h) (No change.)

(i) Automated devices and systems in a pharmacy.

(1) Automated [~~compounding or~~] counting devices. If a pharmacy uses automated ~~compounding or~~] counting devices:

(A) the pharmacy shall have a method to calibrate and verify the accuracy of the automated [~~compounding or~~] counting device and document the calibration and verification on a routine basis;

(B) the devices may be loaded with bulk [~~or unlabeled~~] drugs only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist;

(C) the label of an automated [~~compounding or~~] counting device container containing a bulk drug shall indicate the brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;

(D) records of loading bulk [~~or unlabeled~~] drugs into an automated [~~compounding or~~] counting device shall be maintained to show:

(i) name of the drug, strength, and dosage form;

(ii) manufacturer or distributor;

(iii) manufacturer's lot number;

(iv) [~~manufacturer's~~] expiration date;

(v) date of loading;

(vi) name, initials, or electronic signature of the person loading the automated [~~compounding or~~] counting device; and

(vii) name, initials, or [~~signature or~~] electronic signature of the responsible pharmacist; and

(E) the automated [~~compounding or~~] counting device shall not be used until a pharmacist verifies that the system is properly loaded and affixes his or her name, initials, or electronic signature to the record as specified in subparagraph (D) of this paragraph.

(2) Automated pharmacy dispensing systems.

(A) Authority to use automated pharmacy dispensing systems. A pharmacy may use an automated pharmacy dispensing system to fill prescription drug orders provided that:

(i) the pharmacist-in-charge is responsible for the supervision of the operation of the system;

(ii) the automated pharmacy dispensing system has been tested by the pharmacy and found to dispense accurately. The pharmacy shall make the results of such testing available to the board upon request; and

(iii) the pharmacy will make the automated pharmacy dispensing system available for inspection by the board for the purpose of validating the accuracy of the system.

(B) Automated pharmacy dispensing systems may be stocked or loaded by a pharmacist or by a pharmacy technician or pharmacy technician trainee under the supervision of a pharmacist.

(C) Quality assurance program. A pharmacy which uses an automated pharmacy dispensing system to fill prescription drug orders shall operate according to a [~~written program for~~] quality assurance program of the automated pharmacy dispensing system which:

(i) requires continuous monitoring of the automated pharmacy dispensing system; and

(ii) establishes mechanisms and procedures to test the accuracy of the automated pharmacy dispensing system at least every twelve [~~six~~] months and whenever any upgrade or change is made to the system and documents each such activity.

(D) Policies and procedures of operation.

(i) When an automated pharmacy dispensing system is used to fill prescription drug orders, it shall be operated according to written policies and procedures of operation. The policies and procedures of operation shall:

(I) provide for a pharmacist's review, approval, and accountability for the transmission of each original or new prescription drug order to the automated pharmacy dispensing system before the transmission is made;

(II) provide for access to the automated pharmacy dispensing system for stocking and retrieval of medications which is limited to licensed healthcare professionals or pharmacy technicians acting under the supervision of a pharmacist;

(III) require that a pharmacist checks, verifies, and documents that the correct medication and strength of bulk drugs, prepackaged containers, or manufacturer's unit of use packages were [~~was~~] properly stocked, filled, and loaded in the automated pharmacy dispensing system prior to initiating the fill process; alternatively, an electronic verification system may be used for verification of manufacturer's unit of use packages or prepacked medication previously verified by a pharmacist;

(IV) provide for an accountability record to be maintained that [~~which~~] documents all transactions relative to stocking and removing medications from the automated pharmacy dispensing system;

(V) require a prospective drug regimen review is conducted as specified in subsection (c)(2) of this section; and

(VI) establish and make provisions for documentation of a preventative maintenance program for the automated pharmacy dispensing system.

(ii) A pharmacy that [~~which~~] uses an automated pharmacy dispensing system to fill prescription drug orders shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(E) Recovery Plan. A pharmacy that [~~which~~] uses an automated pharmacy dispensing system to fill prescription drug orders shall maintain a written plan for recovery from a disaster or any other situation which interrupts the ability of the automated pharmacy dispensing system to provide services necessary for the operation of the pharmacy. The written plan for recovery shall include:

(i) planning and preparation for maintaining pharmacy services when an automated pharmacy dispensing system is experiencing downtime;

(ii) procedures for response when an automated pharmacy dispensing system is experiencing downtime; and

(iii) procedures for the maintenance and testing of the written plan for recovery.

(F) Final check of prescriptions dispensed using an automated pharmacy dispensing system. For the purpose of §291.32(c)(2)(D) of this title (relating to Personnel), a pharmacist must perform the final check of all prescriptions prior to delivery to the patient to ensure that the prescription is dispensed accurately as prescribed.

(i) This final check shall be considered accomplished if:

(I) a check of the final product is conducted by a pharmacist after the automated pharmacy dispensing system has completed the prescription and prior to delivery to the patient; or

(II) the following checks are conducted:

(-a-) if the automated pharmacy dispensing system contains bulk stock drugs, a pharmacist verifies that those drugs have been accurately stocked as specified in subparagraph (D)(i)(III) [~~(C)(i)(III)~~] of this paragraph;

(-b-) if the automated pharmacy dispensing system contains manufacturer's unit of use packages or prepackaged medication previously verified by a pharmacist, an electronic verification system has confirmed that the medications have been accurately stocked as specified in [~~clause (i)(III) of this~~] subparagraph (D)(i)(III) of this paragraph;

(-c-) a pharmacist checks the accuracy of the data entry of each original or new prescription drug order entered into the automated pharmacy dispensing system; and

(-d-) an electronic verification process is used to verify the proper prescription label has been affixed to the correct medication container, prepackaged medication or manufacturer unit of use package for the correct patient.

(ii) If the final check is accomplished as specified in clause (i)(II) of this subparagraph, the following additional requirements must be met:[.]

(I) the [~~The~~] dispensing process must be fully automated from the time the pharmacist releases the prescription to the automated pharmacy dispensing system until a completed, labeled prescription ready for delivery to the patient is produced;[.]

(II) the [~~The~~] pharmacy has conducted initial testing and has a continuous quality assurance program which documents that the automated pharmacy dispensing system dispenses accurately as specified in subparagraph (C) [~~subparagraphs (A) and (B)~~] of this paragraph;[.]

(III) the [~~The~~] automated pharmacy dispensing system documents and maintains:

(-a-) the name(s), initials, or identification code(s) of each pharmacist responsible for the checks outlined in clause (i)(II) of this subparagraph; and

(-b-) the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist, pharmacy technician, or pharmacy technician trainee who performs any other portion of the dispensing process; and[.]

(IV) the [~~The~~] pharmacy establishes mechanisms and procedures to test the accuracy of the automated pharmacy dispensing system at least every month rather than every twelve [~~six~~] months as specified in subparagraph (C) [~~(B)~~] of this paragraph.

(3) Automated checking device.

(A) For the purpose of §291.32(c)(2)(D) of this title, the final check of a dispensed prescription shall be considered accomplished using an automated checking device provided a check of the final product is conducted by a pharmacist prior to delivery to the patient or the following checks are performed:

(i) the drug used to fill the order is checked through the use of an automated checking device which verifies that the drug is labeled and packaged accurately; and

(ii) a pharmacist checks the accuracy of each original or new prescription drug order and is responsible for the final check of the order through the automated checking device.

(B) If the final check is accomplished as specified in subparagraph (A) of this paragraph, the following additional requirements must be met:[.]

(i) the [~~The~~] pharmacy has conducted initial testing of the automated checking device and has a continuous quality assurance program which documents that the automated checking device accurately confirms that the correct drug and strength has been labeled with the correct label for the correct patient;[.]

(ii) the [~~The~~] pharmacy documents and maintains:

(I) the name(s), initials, or identification code(s) of each pharmacist responsible for the checks outlined in subparagraph (A)(i) of this paragraph; and

(II) the name(s) initials, or identification code(s) and specific activity(ies) of each pharmacist, or pharmacy technician, or pharmacy technician trainee who perform any other portion of the dispensing process;[.]

(iii) the [~~The~~] pharmacy establishes mechanisms and procedures to test the accuracy of the automated checking device at least monthly; and[.]

(iv) the [~~The~~] pharmacy establishes procedures to ensure that errors identified by the automated checking device may not be overridden by a pharmacy technician and must be reviewed and corrected by a pharmacist.

[~~(4) Automated storage and distribution device. A pharmacy may use an automated storage and distribution device to deliver a previously verified prescription to a patient or patient's agent provided:~~

~~(A) the pharmacist-in-charge is responsible for the supervision of the operation of the system;~~

~~(B) the patient or patient's agent shall be counseled via a direct telephone link by a Texas licensed pharmacist who has access to the complete patient profile prior to the release of any new prescription released from the device;~~

~~(C) the patient or patient's agent may speak with a Texas licensed pharmacist via a direct telephone link for questions regarding their medications;~~

~~(D) the patient or patient's agent is given the option to use the system;~~

~~(E) a notice shall be posted at the automated storage and distribution device with the following information:~~

~~*(i)* the name and address of the pharmacy that verified the previously dispensed prescription; and~~

~~*(ii)* a statement that a pharmacist is available 24 hours a day, 7 days a week through the use of telephonic communication;~~

~~(F) drugs stored in the automated storage and distribution device are stored at proper temperatures;~~

~~(G) the automated storage and distribution device has been tested by the pharmacy and found to dispense prescriptions accurately;~~

~~(H) the automated storage and distribution device may be loaded with previously verified prescriptions only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and supervision of a pharmacist;~~

~~(I) the pharmacy will make the automated storage and distribution device and any testing records of the device available for inspection by the board;~~

~~(J) the automated storage and distribution device must have an adequate security system, including security camera(s), to prevent unauthorized access and to maintain patient confidentiality; and~~

~~(K) the automated storage and distribution device records a digital image of the individual accessing the device to pick-up a prescription and such record is maintained by the pharmacy for two years.~~]

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 19, 2018.

TRD-201805532
Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: February 3, 2019
For further information, please call: (512) 305-8010

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22 TAC §291.35

The Texas State Board of Pharmacy proposes amendments to §291.35, concerning Official Prescription Requirements. The amendments, if adopted, update the citation reference regarding the requirement for the use of official prescriptions for Schedule II controlled substances in Class A pharmacies.

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to provide clear regulatory language by updating an outdated law citation reference. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendment will be in effect, Ms. Benz has determined the following:

(1) The proposed rule does not create or eliminate a government program;

(2) Implementation of the proposed rule does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed rule does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed rule does not require an increase or decrease in fees paid to the agency;

(5) The proposed rule does not create a new regulation;

(6) The proposed rule does not limit or expand an existing regulation;

(7) The proposed rule does not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed rule does not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Assistant General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., February 3, 2019.

The amendments are proposed under §§551.002, 554.051, and 562.1011 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.35. Official Prescription Requirements.

Class A pharmacies are subject to the rules set forth in chapter 315 of this title (relating to Controlled Substances). [~~The Texas State Board of Pharmacy adopts by reference the rules promulgated by the Texas Department of Public Safety, which are set forth in Subchapter D of 37 TAC §§13.71 - 13.86 concerning official prescriptions.~~]

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 19, 2018.

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Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: February 3, 2019
For further information, please call: (512) 305-8010

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SUBCHAPTER D. INSTITUTIONAL PHARMACY (CLASS C)

22 TAC §291.75

The Texas State Board of Pharmacy proposes amendments to §291.75, concerning Records. The amendments, if adopted, update citation references regarding outpatient records, outpatient prescription forms, and official prescriptions for Schedule II controlled substances, remove references to nalbuphine (e.g., Nubain) from the electronic recordkeeping requirements for distribution and return of controlled substances, and correct grammatical errors.

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to provide clear regulatory language by updating outdated citation references and by removing outdated drug references in the requirements for electronic records for distribution and return of controlled substances. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendment will be in effect, Ms. Benz has determined the following:

(1) The proposed rule does not create or eliminate a government program;

(2) Implementation of the proposed rule does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed rule does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed rule does not require an increase or decrease in fees paid to the agency;

(5) The proposed rule does not create a new regulation;

(6) The proposed rule does not limit or expand an existing regulation;

(7) The proposed rule does not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed rule does not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Assistant General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., February 3, 2019.

The amendments are proposed under §§551.002, 554.051, and 562.1011 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551- 569, Texas Occupations Code.

§291.75. Records.

(a) Maintenance of records.

(1) Every inventory or other record required to be kept under the provisions of §291.71 of this title (relating to Purpose), §291.72 of this title (relating to Definitions), §291.73 of this title (relating to Personnel), §291.74 of this title (relating to Operational Standards), and this section contained in Institutional Pharmacy (Class C) shall be:

(A) kept by the institutional pharmacy and be available, for at least two years from the date of such inventory or record, for inspecting and copying by the board or its representative, and to other authorized local, state, or federal law enforcement agencies; and

(B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in a mutually agreeable electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this subsection, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(2) Records of controlled substances listed in Schedules [~~Schedule~~] I and II shall be maintained separately from all other records of the pharmacy.

(3) Records of controlled substances listed in Schedules III - V shall be maintained separately or readily retrievable from all other records of the pharmacy. For purposes of this subsection, readily retrievable means that the controlled substances shall be asterisked, redlined, or in some other manner readily identifiable apart from all other items appearing on the record.

(4) Records, except when specifically required to be maintained in original or hard-copy form, may be maintained in an alternative data retention system, such as a data processing or direct imaging system, e.g., microfilm or microfiche, provided:

(A) the records in the alternative data retention system contain all of the information required on the manual record; and

(B) the alternative data retention system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(b) Outpatient records.

(1) Outpatient records shall be maintained as provided in §291.34 [~~of this title~~] (relating to Records), and §291.35 [~~of this title~~] (relating to Official Prescription Records), in chapter 281, subchapter B of this title relating to contained in Community Pharmacy (Class A).

(2) Outpatient prescriptions, including, but not limited to, furlough and discharge prescriptions, that are written by a [~~the~~] practitioner must be written on a form which meets the requirements of §291.34(b)(7)(A) of this title [~~the Act, §562.006~~]. Medication order forms or copies thereof do not meet the requirements for outpatient forms.

(3) Controlled substances listed in Schedule II must be written on an official prescription form in accordance with the Texas Controlled Substances Act, §481.075, and rules promulgated pursuant to the Texas Controlled Substances Act, unless exempted by chapter 315 of this title (relating to Controlled Substances) [~~the Texas controlled substances regulations, 37 TAC §13.74 (relating to Exceptions to Use of Forms)~~]. Outpatient prescriptions for Schedule II controlled substances that are exempted from the official prescription requirement must be manually signed by the practitioner.

(c) Patient records.

(1) Original medication orders.

(A) Each original medication order shall bear the following information:

(i) patient name and room number or identification number;

(ii) drug name, strength, and dosage form;

(iii) directions for use;

(iv) date; and

(v) signature or electronic signature of the practitioner or that of his or her authorized agent.

(B) Original medication orders [~~order~~] shall be maintained with the medication administration records of the patients.

(2) Patient medication records (PMR). A patient medication record shall be maintained for each patient of the facility. The PMR shall contain at a minimum the following information.

(A) Patient information:

(i) patient name and room number or identification number;

(ii) gender, and date of birth or age;

(iii) weight and height;

(iv) known drug sensitivities and allergies to drugs and/or food;

(v) primary diagnoses and chronic conditions;

(vi) primary physician; and

(vii) other drugs the patient is receiving.

(B) Medication order information:

(i) date of distribution;

(ii) drug name, strength, and dosage form; and

(iii) directions for use.

(3) Controlled substances records. Controlled substances records shall be maintained as follows.

(A) All records for controlled substances shall be maintained in a readily retrievable manner.

(B) Controlled substances records shall be maintained in a manner to establish receipt and distribution of all controlled substances.

(4) Schedule II controlled substances records. Records of controlled substances listed in Schedule II shall be maintained as follows.

(A) Records of controlled substances listed in Schedule II shall be maintained separately from records of controlled substances in Schedules III, IV, and V, and all other records.

(B) An institutional pharmacy shall maintain a perpetual inventory of any controlled substance listed in Schedule II.

(C) Distribution records for controlled substances listed in Schedule II shall bear the following information:

(i) patient's name;

(ii) prescribing or attending practitioner;

(iii) name of drug, dosage form, and strength;

(iv) time and date of administration to patient and quantity administered;

(v) name, initials, or electronic signature of the individual administering the controlled substance;

(vi) returns to the pharmacy; and

(vii) waste (waste is required to be witnessed and cosigned, electronically or manually, by another individual).

(5) Floor stock records.

(A) Distribution records for Schedules [~~Schedule~~] II - V controlled substances floor stock shall include the following information:

(i) patient's name;

(ii) prescribing or attending practitioner;

(iii) name of controlled substance, dosage form, and strength;

(iv) time and date of administration to patient;

(v) quantity administered;

(vi) name, initials, or electronic signature of the individual administering drug;

(vii) returns to the pharmacy; and

(viii) waste (waste is required to be witnessed and cosigned, manually or electronically, by another individual).

(B) The record required by subparagraph (A) of this paragraph shall be maintained separately from patient records.

(C) A pharmacist shall review distribution records with medication orders on a periodic basis to verify proper usage of drugs, not to exceed 30 days between such reviews.

(6) General requirements for records maintained in a data processing system.

(A) Noncompliance with data processing requirements. If a hospital pharmacy's data processing system is not in compliance with the Board's requirements, the pharmacy must maintain a manual recordkeeping system.

(B) Requirements for back-up systems. The facility shall maintain a back-up copy of information stored in the data processing system using disk, tape, or other electronic back-up system and update this back-up copy on a regular basis, at least monthly, to assure that data is not lost due to system failure.

(C) Change or discontinuance of a data processing system.

(i) Records of distribution and return for all controlled substances [~~and nalbuphine (e.g., Nubain)~~]. A pharmacy that changes or discontinues use of a data processing system must:

(I) transfer the records to the new data processing system; or

(II) purge the records to a printout which contains the same information as required on the audit trail printout as specified in paragraph (7)(B) of this subsection. The information on this printout shall be sorted and printed by drug name and list all distributions/returns chronologically.

(ii) Other records. A pharmacy that changes or discontinues use of a data processing system must:

(I) transfer the records to the new data processing system; or

(II) purge the records to a printout which contains all of the information required on the original document.

(iii) Maintenance of purged records. Information purged from a data processing system must be maintained by the pharmacy for two years from the date of initial entry into the data processing system.

(D) Loss of data. The pharmacist-in-charge shall report to the board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.

(7) Data processing system maintenance of records for the distribution and return of all controlled substances [~~and nalbuphine (e.g., Nubain)~~] to the pharmacy.

(A) Each time a controlled substance [~~or nalbuphine (e.g., Nubain)~~] is distributed from or returned to the pharmacy, a record of such distribution or return shall be entered into the data processing system.

(B) The data processing system shall have the capacity to produce a hard copy printout of an audit trail of drug distribution and return for any strength and dosage form of a drug (by either brand or generic name or both) during a specified time period. This printout shall contain the following information:

(i) patient's name and room number or patient's facility identification number;

(ii) prescribing or attending practitioner's name;

(iii) name, strength, and dosage form of the drug product actually distributed;

(iv) total quantity distributed from and returned to the pharmacy;

(v) if not immediately retrievable via electronic image, the following shall also be included on the printout:

(I) prescribing or attending practitioner's address; and

(II) practitioner's DEA registration number, if the medication order is for a controlled substance.

(C) An audit trail printout for each strength and dosage form of the [these] drugs distributed during the preceding month shall be produced at least monthly and shall be maintained in a separate file at the facility unless the pharmacy complies with subparagraph (D) of this paragraph. The information on this printout shall be sorted by drug name and list all distributions/returns for that drug chronologically.

(D) The pharmacy may elect not to produce the monthly audit trail printout if the data processing system has a workable (electronic) data retention system which can produce an audit trail of drug distribution and returns for the preceding two years. The audit trail required in this paragraph shall be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy, or other authorized local, state, or federal law enforcement or regulatory agencies.

(8) Failure to maintain records. Failure to provide records set out in this subsection, either on site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep and maintain records.

(9) Data processing system downtime. In the event that a hospital pharmacy that [which] uses a data processing system experiences system downtime, the pharmacy must have an auxiliary procedure which will ensure that all data is retained for on-line data entry as soon as the system is available for use again.

(10) Ongoing clinical pharmacy program records. If a pharmacy has an ongoing clinical pharmacy program and allows pharmacy technicians to verify the accuracy of work performed by other pharmacy technicians, the pharmacy must have a record of the pharmacy technicians and the duties performed.

(d) Distribution of controlled substances to another registrant. A pharmacy may distribute controlled substances to a practitioner, another pharmacy, or other registrant, without being registered to distribute, under the following conditions: [:]

(1) The registrant to whom the controlled substance is to be distributed is registered under the Controlled Substances Act to dispense that controlled substance; and [;]

(2) The total number of dosage units of controlled substances distributed by a pharmacy may not exceed 5.0% of all controlled substances dispensed or distributed by the pharmacy during the 12-month period in which the pharmacy is registered; if at any time it does exceed 5.0%, the pharmacy is required to obtain an additional registration to distribute controlled substances.

(3) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be maintained which indicates:

(A) the actual date of distribution;

(B) the name, strength, and quantity of controlled substances distributed;

(C) the name, address, and DEA registration number of the distributing pharmacy; and

(D) the name, address, and DEA registration number of the pharmacy, practitioner, or other registrant to whom the controlled substances are distributed.

(4) If the distribution is for a Schedule I or II controlled substance, the following is applicable.

(A) The pharmacy, practitioner or other registrant who is receiving the controlled substances shall issue copy 1 and copy 2 of a DEA order form (DEA 222) to the distributing pharmacy.

(B) The distributing pharmacy shall:

(i) complete the area on the DEA order form (DEA 222) titled TO BE FILLED IN BY SUPPLIER;

(ii) maintain copy 1 of the DEA order form (DEA 222) at the pharmacy for two years; and

(iii) forward copy 2 of the DEA order form (DEA 222) to the divisional office of the Drug Enforcement Administration.

(e) Other records. Other records to be maintained by a pharmacy:

(1) a log of the initials or identification codes which will identify pharmacy personnel by name (the initials or identification code shall be unique to ensure that each person can be identified, i.e., identical initials or identification codes cannot be used). Such log shall be maintained at the pharmacy for at least seven years from the date of the transaction;

(2) copy 3 of DEA order form (DEA 222) which has been properly dated, initialed, and filed, and all copies of each unaccepted or defective order form and any attached statements or other documents;

(3) a hard copy of the power of attorney to sign DEA 222 order forms (if applicable);

(4) suppliers' invoices of dangerous drugs and controlled substances; a pharmacist shall verify that the controlled drugs listed on the invoices were actually received by clearly recording his/her initials and the actual date of receipt of the controlled substances;

(5) suppliers' credit memos for controlled substances and dangerous drugs;

(6) a hard copy of inventories required by §291.17 of this title (relating to Inventory Requirements) except that a perpetual inventory of controlled substances listed in Schedule II may be kept in a data processing system if the data processing system is capable of producing a hard copy of the perpetual inventory on-site;

(7) hard copy reports of surrender or destruction of controlled substances and/or dangerous drugs to an appropriate state or federal agency;

(8) a hard copy Schedule V nonprescription register book;

(9) records of distribution of controlled substances and/or dangerous drugs to other pharmacies, practitioners, or registrants; and

(10) a hard copy of any notification required by the Texas Pharmacy Act or these sections including, but not limited to, the following:

(A) reports of theft or significant loss of controlled substances to DEA, DPS, and the board;

(B) notifications of a change in pharmacist-in-charge of a pharmacy; and

(C) reports of a fire or other disaster which may affect the strength, purity, or labeling of drugs, medications [~~medication~~], devices, or other materials used in diagnosis or treatment of injury, illness, and disease.

(f) Permission to maintain central records. Any pharmacy that uses a centralized recordkeeping system for invoices and financial data shall comply with the following procedures.

(1) Controlled substance records. Invoices and financial data for controlled substances may be maintained at a central location provided the following conditions are met: [~~,~~]

(A) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by registered or certified mail to the divisional director of the Drug Enforcement Administration as required by Title 21, Code of Federal Regulations, §1304.04(a), and submits a copy of this written notification to the board [~~Texas State Board of Pharmacy~~]. Unless the registrant is informed by the divisional director of the Drug Enforcement Administration that permission to keep central records is denied, the pharmacy may maintain central records commencing 14 days after receipt of notification by the divisional director;[~~,~~]

(B) The pharmacy maintains a copy of the notification required in subparagraph (A) of this paragraph; and[~~,~~]

(C) The records to be maintained at the central record location shall not include executed DEA order forms, prescription drug orders, or controlled substance inventories, which shall be maintained at the pharmacy.

(2) Dangerous drug records. Invoices and financial data for dangerous drugs may be maintained at a central location.

(3) Access to records. If the records are kept on microfilm, computer media, or in any form requiring special equipment to render the records easily readable, the pharmacy shall provide access to such equipment with the records.

(4) Delivery of records. The pharmacy agrees to deliver all or any part of such records to the pharmacy location within two business days of written request of a board agent or any other authorized official.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director
Texas State Board of Pharmacy
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For further information, please call: (512) 305-8010

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SUBCHAPTER G. SERVICES PROVIDED BY PHARMACIES

22 TAC §291.121

The Texas State Board of Pharmacy proposes amendments to §291.121, concerning Remote Pharmacy Services. The amendments, if adopted, provide standards and requirements for the provision of remote pharmacy services using automated storage and delivery systems, including definitions, general requirements, operational standards, and records requirements.

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to provide standards for the provision of remote pharmacy services using automated storage and delivery systems by Class A and Class C pharmacies. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendment will be in effect, Ms. Benz has determined the following:

(1) The proposed rule does not create or eliminate a government program;

(2) Implementation of the proposed rule does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed rule does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed rule does not require an increase or decrease in fees paid to the agency;

(5) The proposed rule does not create a new regulation;

(6) The proposed rule expands an existing regulation;

(7) The proposed rule does not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed rule may positively affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Assistant General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., February 3, 2019.

The amendments are proposed under §§551.002, 554.051, and 562.1011 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551- 569, Texas Occupations Code.

§291.121. Remote Pharmacy Services.

(a) - (c) (No change.)

(d) Remote pharmacy services using automated storage and delivery systems.

(1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy services by a Class A or Class C pharmacy in a facility that is not at the same location as the Class A or Class C pharmacy through an automated storage and delivery system.

(2) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act.

(A) Automated storage and delivery system--A mechanical system that delivers dispensed prescription drugs to patients at a remote delivery site and maintains related transaction information.

(B) Deliver or delivery--The actual, constructive, or attempted transfer of a prescription drug or device or controlled substance from one person to another, whether or not for a consideration.

(C) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(D) Remote delivery site--A location at which remote pharmacy services are provided using an automated storage and delivery system.

(E) Provider pharmacy--The community pharmacy (Class A) or the institutional pharmacy (Class C) providing remote pharmacy services.

(F) Remote pharmacy service--The provision of pharmacy services, including the storage and delivery of prescription drugs, in remote delivery sites.

(3) General requirements for a provider pharmacy to provide remote pharmacy services using an automated storage and delivery system to deliver a previously verified prescription that is dispensed by the provider pharmacy to a patient or patient's agent.

(A) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy operations involving the automated storage and delivery system located at the remote delivery site including supervision of the automated storage and delivery system and compliance with this section.

(B) The patient or patient's agent shall receive counseling via a direct link to audio or video communication by a Texas licensed pharmacist who has access to the complete patient medication record (patient profile) maintained by the provider pharmacy prior to the release of any new prescription released from the system.

(C) A pharmacist shall be accessible at all times to respond to patients' or other health professionals' questions and needs pertaining to drugs delivered through the use of the automated storage and delivery system. Such access may be through a 24 hour pager service or telephone which is answered 24 hours a day.

(D) The patient or patient's agent shall be given the option whether to use the system.

(E) An electronic notice shall be provided to the patient or patient's agent at the remote delivery site with the following information:

(i) the name and address of the pharmacy that verified the previously dispensed prescription; and

(ii) a statement that a pharmacist is available 24 hours a day, 7 days a week through the use of telephonic communication.

(F) Drugs stored in the automated storage and distribution system shall be stored at proper temperatures, as defined in the USP/NF and §291.15 of this title (relating to Storage of Drugs).

(G) A provider pharmacy may only provide remote pharmacy services using an automated storage and delivery system to patients at a board-approved remote delivery site.

(H) A provider pharmacy may provide remote pharmacy services at more than one remote delivery site.

(I) Before providing remote pharmacy services, the automated storage and delivery system at the remote delivery site must be tested by the provider pharmacy and found to deliver accurately. The provider pharmacy shall make the results of such testing available to the board upon request.

(J) A provider pharmacy which is licensed as an institutional (Class C) pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title (relating to Definitions, Personnel, Operational Standards, and Records for Class A (Community) Pharmacies) and this section.

(4) Operational standards.

(A) Application to provide remote pharmacy services using an automated storage and delivery system.

(i) A community (Class A) or institutional (Class C) pharmacy shall file a completed application containing all information required by the board to provide remote pharmacy services using an automated storage and delivery system.

(ii) Such application shall be resubmitted every two years in conjunction with the application for renewal of the provider pharmacy's license.

(iii) Upon approval of the application, the provider pharmacy will be sent a certificate which must be displayed at the provider pharmacy.

(B) Notification requirements.

(i) A provider pharmacy shall notify the board in writing within ten days of a discontinuance of service.

(ii) A provider pharmacy shall comply with appropriate controlled substance registrations for each remote delivery site if dispensed controlled substances are maintained within an automated storage and delivery system at the facility.

(iii) A provider pharmacy shall file an application for change of location and/or name of a remote delivery site as specified in §291.3 of this title (relating to Notifications).

(C) Environment/Security.

(i) A provider pharmacy shall only store dispensed drugs at a remote delivery site within an automated storage and delivery system which is locked by key, combination or other mechanical or electronic means so as to prohibit access by unauthorized personnel.

(ii) Access to the automated storage and delivery system shall be limited to pharmacists, and pharmacy technicians or pharmacy technician trainees under the direct supervision of a pharmacist who:

(I) are designated in writing by the pharmacist-in-charge; and

(II) have completed documented training concerning their duties associated with the automated storage and delivery system.

(iii) Drugs shall be stored in compliance with the provisions of §291.15 (relating to Storage of Drugs) and §291.33(c)(8) (relating to Returning Undelivered Medication to Stock) of this title, including the requirements for temperature and the return of undelivered medication to stock.

(iv) the automated storage and delivery system must have an adequate security system, including security camera(s), to prevent unauthorized access and to maintain patient confidentiality.

(D) Stocking an automated storage and delivery system. Stocking of dispensed prescriptions in an automated storage and delivery system shall be completed under the supervision of a pharmacist.

(E) Quality assurance program. A pharmacy that provides pharmacy services through an automated storage and delivery system at a remote delivery site shall operate according to a written program for quality assurance of the automated storage and delivery system which:

(i) requires continuous supervision of the automated storage and delivery system; and

(ii) establishes mechanisms and procedures to routinely test the accuracy of the automated storage and delivery system at a minimum of every six months and whenever any upgrade or change is made to the system and documents each such activity.

(F) Policies and procedures of operation.

(i) A pharmacy that provides pharmacy services through an automated storage and delivery system at a remote delivery site shall operate according to written policies and procedures. The policy and procedure manual shall include, but not be limited to, the following:

(ii) A pharmacy that provides pharmacy services through an automated storage and delivery system at a remote delivery site shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(iii) A pharmacy providing remote pharmacy services using an automated storage and delivery system shall maintain a written plan for recovery from an event which interrupts the ability of the automated storage and delivery system to deliver dispense prescription drugs. The written plan for recovery shall include:

(I) planning and preparation for maintaining pharmacy services when an automated storage and delivery system is experiencing downtime;

(II) procedures for response when an automated storage and delivery system is experiencing downtime; and

(III) procedures for the maintenance and testing of the written plan for recovery.

(5) Records.

(A) Maintenance of records.

(i) Every record required under this section must be:

(I) kept by the provider pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(II) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(ii) The provider pharmacy shall have a workable (electronic) data retention system which can produce a separate audit trail of drug delivery and retrieval transactions at each remote delivery site for the preceding two years.

(B) Transaction information.

(i) The automated storage and delivery system shall electronically record all transactions involving drugs stored in, removed, or delivered from the system.

(ii) Records of delivery from an automated storage and delivery system for a patient shall be maintained by the provider pharmacy and include the:

(I) identity of the system accessed;

(II) identification of the individual accessing the system;

(III) date of transaction;

(IV) prescription number, drug name, strength, dosage form;

(V) number of prescriptions retrieved;

(VI) name of the patient for whom the prescription was retrieved;

(VII) name of prescribing practitioner; and

(VIII) name of pharmacist responsible for consultation with the patient, if required, and documentation that the consultation was performed.

(iii) Records of stocking or removal from an automated storage and delivery system shall be maintained by the pharmacy and include the:

(I) date;

(II) prescription number;

(III) name of the patient;

(IV) drug name;

(V) number of dispensed prescription packages stocked or removed;

(VI) name, initials, or identification code of the person stocking or removing dispensed prescription packages from the system; and

(VII) name, initials, or identification code of the pharmacist who checks and verifies that the system has been accurately filled;

(C) the pharmacy shall make the automated storage and delivery system and any records of the system, including testing records, available for inspection by the board; and

(D) the automated storage and delivery system records a digital image of the individual accessing the system to pick-up a prescription and such record is maintained by the pharmacy for two years.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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22 TAC §291.131

The Texas State Board of Pharmacy proposes amendments to §291.131, concerning Pharmacies Compounding Non-Sterile Preparations. The amendments, if adopted, add definitions for active pharmaceutical ingredient, commercially available product, easily substitutable dosage strength, and essentially a copy of commercially available product.

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to provide clear regulatory language by including definitions for terms used throughout the section. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendment will be in effect, Ms. Benz has determined the following:

(1) The proposed rule does not create or eliminate a government program;

(2) Implementation of the proposed rule does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed rule does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed rule does not require an increase or decrease in fees paid to the agency;

(5) The proposed rule does not create a new regulation;

(6) The proposed rule does not limit or expand an existing regulation;

(7) The proposed rule does not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed rule does not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Assistant General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., February 3, 2019.

The amendments are proposed under §§551.002, 554.051, and 562.1011 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551- 569, Texas Occupations Code.

§291.131. Pharmacies Compounding Non-Sterile Preparations.

(a) Purpose. Pharmacies compounding non-sterile preparations, prepackaging pharmaceutical products and distributing those products shall comply with all requirements for their specific license classification and this section. The purpose of this section is to provide standards for the:

(1) compounding of non-sterile preparations pursuant to a prescription or medication order for a patient from a practitioner in Class A (Community), Class C (Institutional), and Class E (Non-resident) pharmacies;

(2) compounding, dispensing, and delivery of a reasonable quantity of a compounded non-sterile preparation in a Class A (Community), Class C (Institutional), and Class E (Non-resident) pharmacies to a practitioner's office for office use by the practitioner;

(3) compounding and distribution of compounded non-sterile preparations by a Class A (Community) pharmacy for a Class C (Institutional) pharmacy; and

(4) compounding of non-sterile preparations by a Class C (Institutional) pharmacy and the distribution of the compounded preparations to other Class C (Institutional) pharmacies under common ownership.

(b) Definitions. In addition to the definitions for specific license classifications, the following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Active pharmaceutical ingredient--The substance in a drug product that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or function of the body.

(2) [~~(1)~~] Beyond-use date--The date or time after which the compounded non-sterile preparation shall not be stored or transported or begin to be administered to a patient. The beyond-use date is determined from the date or time when the preparation was compounded.

(3) Commercially available product--A drug product that is a marketed drug product or available on the market, and subject to federal requirements relating to approval, labeling, and Current Good Manufacturing Practice (CGMP) requirements, the federal copies restrictions under section 503A of the Federal Food Drug and Cosmetic Act, and the copy restrictions described under subsections (d)(1)(C) and (D) of this section.

(4) [~~(2)~~] Component--Any ingredient intended for use in the compounding of a drug preparation, including those that may not appear in such preparation.

(5) [~~(3)~~] Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or device:

(A) as the result of a practitioner's prescription drug or medication order, based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(B) for administration to a patient by a practitioner as the result of a practitioner's initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(C) in anticipation of prescription drug or medication orders based on routine, regularly observed prescribing patterns; or

(D) for or as an incident to research, teaching, or chemical analysis and not for sale or dispensing, except as allowed under §562.154 or Chapter 563 of the Occupations Code.

(6) Easily substitutable dosage strength--A dosage strength of a compounded drug preparation that can be achieved by the administration of fractional or multiple doses of a commercially available drug product.

(7) Essentially a copy of a commercially available product--A compounded preparation:

(A) that has the same active pharmaceutical ingredient(s) as the commercially available drug product;

(B) containing an active pharmaceutical ingredient that has:

(i) the same or similar dosage strength; or

(ii) an easily substitutable dosage strength; and

(C) for which the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug preparation.

(8) [~~(4)~~] Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of 105 degrees F (41 degrees C).

(9) [~~(5)~~] Reasonable quantity--An amount of a compounded drug that:

(A) does not exceed the amount a practitioner anticipates may be used in the practitioner's office or facility before the beyond use date of the drug;

(B) is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice; and

(C) for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.

(10) [~~(6)~~] SOPs--Standard operating procedures.

(11) [~~(7)~~] USP/NF--The current edition of the United States Pharmacopeia/National Formulary.

(c) Personnel.

(1) Pharmacist-in-charge. In addition to the responsibilities for the specific class of pharmacy, the pharmacist-in-charge shall have the responsibility for, at a minimum, the following concerning non-sterile compounding:

(A) determining that all personnel involved in non-sterile compounding possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken or supervised;

(B) determining that all personnel involved in non-sterile compounding obtain continuing education appropriate for the type of compounding done by the personnel;

(C) assuring that the equipment used in compounding is properly maintained;

(D) maintaining an appropriate environment in areas where non-sterile compounding occurs; and

(E) assuring that effective quality control procedures are developed and followed.

(2) Pharmacists. Special requirements for non-sterile compounding.

(A) All pharmacists engaged in compounding shall:

(i) possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken or supervised; and

(ii) obtain continuing education appropriate for the type of compounding done by the pharmacist.

(B) A pharmacist shall inspect and approve all components, drug product containers, closures, labeling, and any other materials involved in the compounding process.

(C) A pharmacist shall review all compounding records for accuracy and conduct in-process and final checks to ensure that errors have not occurred in the compounding process.

(D) A pharmacist is responsible for the proper maintenance, cleanliness, and use of all equipment used in the compounding process.

(3) Pharmacy technicians and pharmacy technician trainees. All pharmacy technicians and pharmacy technician trainees engaged in non-sterile compounding shall:

(A) possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken;

(B) obtain continuing education appropriate for the type of compounding done by the pharmacy technician or pharmacy technician trainee; and

(C) perform compounding duties under the direct supervision of and responsible to a pharmacist.

(4) Training.

(A) All training activities shall be documented and covered by appropriate SOPs as outlined in subsection (d)(8)(A) of this section.

(B) All personnel involved in non-sterile compounding shall be well trained and must participate in continuing relevant training programs.

(d) Operational Standards.

(1) General requirements.

(A) Non-sterile drug preparations may be compounded in licensed pharmacies:

(i) upon presentation of a practitioner's prescription drug or medication order based on a valid pharmacist/patient/prescriber relationship;

(ii) in anticipation of future prescription drug or medication orders based on routine, regularly observed prescribing patterns; or

(iii) in reasonable quantities for office use by a practitioner and for use by a veterinarian.

(B) Non-sterile compounding in anticipation of future prescription drug or medication orders must be based upon a history of receiving valid prescriptions issued within an established pharmacist/patient/prescriber relationship, provided that in the pharmacist's professional judgment the quantity prepared is stable for the anticipated shelf time.

(i) The pharmacist's professional judgment shall be based on the criteria used to determine a beyond-use date outlined in paragraph (5)(C) of this subsection.

(ii) Documentation of the criteria used to determine the stability for the anticipated shelf time must be maintained and be available for inspection.

(iii) Any preparation compounded in anticipation of future prescription drug or medication orders shall be labeled. Such label shall contain:

(I) name and strength of the compounded preparation or list of the active ingredients and strengths;

(II) facility's lot number;

(III) beyond-use date as determined by the pharmacist using appropriate documented criteria as outlined in paragraph (5)(C) of this subsection; and

(IV) quantity or amount in the container.

(C) Commercially available products may be compounded for dispensing to individual patients provided the following conditions are met:

(i) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet patient's needs;

(ii) the pharmacy maintains documentation that the product is not reasonably available due to a drug shortage or unavailability from the manufacturer; and

(iii) the prescribing practitioner has requested that the drug be compounded as described in subparagraph (D) of this paragraph.

(D) A pharmacy may not compound preparations that are essentially copies of commercially available products (e.g., the preparation is dispensed in a strength that is only slightly different from a commercially available product) unless the prescribing practitioner specifically orders the strength or dosage form and specifies why the patient needs the particular strength or dosage form of the preparation. The prescribing practitioner shall provide documentation of a patient specific medical need and the preparation produces a clinically significant therapeutic response (e.g. the physician requests an alternate product due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available. The unavailability of such drug product must be documented prior to compounding. The methodology for documenting unavailability includes maintaining a copy of the wholesaler's notification showing back-ordered, discontinued, or out-of-stock items. This documentation must be available in hard-copy or electronic format for inspection by the board.

(E) A pharmacy may enter into an agreement to compound and dispense prescription/medication orders for another pharmacy provided the pharmacy complies with the provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).

(F) Compounding pharmacies/pharmacists may advertise and promote the fact that they provide non-sterile prescription compounding services, which may include specific drug products and classes of drugs.

(G) A pharmacy may not compound veterinary preparations for use in food producing animals except in accordance with federal guidelines.

(H) A pharmacist may add flavoring to a prescription at the request of a patient, the patient's agent, or the prescriber. The pharmacist shall label the flavored prescription with a beyond-use-date that shall be no longer than fourteen days if stored in a refrigerator unless otherwise documented. Documentation of beyond-use-dates longer than fourteen days shall be maintained by the pharmacy electronically or manually and made available to agents of the board on request. A pharmacist may not add flavoring to an over-the-counter product at the request of a patient or patient's agent unless the pharmacist obtains a prescription for the over-the-counter product from the patient's practitioner.

(2) Library. In addition to the library requirements of the pharmacy's specific license classification, a pharmacy shall maintain a current copy, in hard-copy or electronic format, of Chapter 795 of the USP/NF concerning Pharmacy Compounding Non-Sterile Preparations.

(3) Environment.

(A) Pharmacies regularly engaging in compounding shall have a designated and adequate area for the safe and orderly compounding of non-sterile preparations, including the placement of equipment and materials. Pharmacies involved in occasional compounding shall prepare an area prior to each compounding activity which is adequate for safe and orderly compounding.

(B) Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of a drug compounding operation.

(C) A sink with hot and cold running water, exclusive of rest room facilities, shall be accessible to the compounding areas and be maintained in a sanitary condition. Supplies necessary for adequate washing shall be accessible in the immediate area of the sink and include:

(i) soap or detergent; and

(ii) air-driers or single-use towels.

(D) If drug products which require special precautions to prevent contamination, such as penicillin, are involved in a compounding operation, appropriate measures, including dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its use for the preparation of other drug products, must be used in order to prevent cross-contamination.

(4) Equipment and Supplies. The pharmacy shall:

(A) have a Class A prescription balance, or analytical balance and weights which shall be properly maintained and subject to periodic inspection by the Texas State Board of Pharmacy; and

(B) have equipment and utensils necessary for the proper compounding of prescription drug or medication orders. Such equipment and utensils used in the compounding process shall be:

(i) of appropriate design and capacity, and be operated within designed operational limits;

(ii) of suitable composition so that surfaces that contact components, in-process material, or drug products shall not be re-

active, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the desired result;

(iii) cleaned and sanitized immediately prior and after to each use; and

(iv) routinely inspected, calibrated (if necessary), or checked to ensure proper performance.

(5) Labeling. In addition to the labeling requirements of the pharmacy's specific license classification, the label dispensed or distributed pursuant to a prescription drug or medication order shall contain the following.

(A) The generic name(s) or the official name(s) of the principal active ingredient(s) of the compounded preparation.

(B) A statement that the preparation has been compounded by the pharmacy. (An auxiliary label may be used on the container to meet this requirement).

(C) A beyond-use date after which the compounded preparation should not be used. The beyond-use date shall be determined as outlined in Chapter 795 of the USP/NF concerning Pharmacy Compounding Non-Sterile Preparations including the following:

(i) The pharmacist shall consider:

(I) physical and chemical properties of active ingredients;

(II) use of preservatives and/or stabilizing agents;

(III) dosage form;

(IV) storage containers and conditions; and

(V) scientific, laboratory, or reference data from a peer reviewed source and retained in the pharmacy. The reference data should follow the same preparation instructions for combining raw materials and packaged in a container with similar properties.

(ii) In the absence of stability information applicable for a specific drug or preparation, the following maximum beyond-use dates are to be used when the compounded preparation is packaged in tight, light-resistant containers and stored at controlled room temperatures.

(I) Nonaqueous liquids and solid formulations (Where the manufactured drug product is the source of active ingredient): 25% of the time remaining until the product's expiration date or 6 months, whichever is earlier.

(II) Water-containing formulations (Prepared from ingredients in solid form): Not later than 14 days when refrigerated between 2 - 8 degrees Celsius (36 - 46 degrees Fahrenheit).

(III) All other formulations: Intended duration of therapy or 30 days, whichever is earlier.

(iii) Beyond-use date limits may be exceeded when supported by valid scientific stability information for the specific compounded preparation.

(6) Written drug information. Written information about the compounded preparation or its major active ingredient(s) shall be given to the patient at the time of dispensing. A statement which indicates that the preparation was compounded by the pharmacy must be included in this written information. If there is no written information available, the patient should be advised that the drug has been compounded and how to contact a pharmacist, and if appropriate the prescriber, concerning the drug.

(7) Drugs, components, and materials used in non-sterile compounding.

(A) Drugs used in non-sterile compounding shall be a USP/NF grade substances manufactured in an FDA-registered facility.

(B) If USP/NF grade substances are not available, or when food, cosmetics, or other substances are, or must be used, the substance shall be of a chemical grade in one of the following categories:

(i) Chemically Pure (CP);

(ii) Analytical Reagent (AR); or

(iii) American Chemical Society (ACS); or

(iv) Food Chemical Codex; or

(C) If a drug, component or material is not purchased from a FDA-registered facility, the pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the supplier and the pharmacist shall compare the monograph of drugs in a similar class to the Certificate of Analysis.

(D) A manufactured drug product may be a source of active ingredient. Only manufactured drugs from containers labeled with a batch control number and a future expiration date are acceptable as a potential source of active ingredients. When compounding with manufactured drug products, the pharmacist must consider all ingredients present in the drug product relative to the intended use of the compounded preparation.

(E) All components shall be stored in properly labeled containers in a clean, dry area, under proper temperatures.

(F) Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug product beyond the desired result.

(G) Components, drug product containers, and closures shall be rotated so that the oldest stock is used first.

(H) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug product.

(I) A pharmacy may not compound a preparation that contains ingredients appearing on a federal Food and Drug Administration list of drug products withdrawn or removed from the market for safety reasons.

(8) Compounding process.

(A) All significant procedures performed in the compounding area shall be covered by written SOPs designed to ensure accountability, accuracy, quality, safety, and uniformity in the compounding process. At a minimum, SOPs shall be developed for:

(i) the facility;

(ii) equipment;

(iii) personnel;

(iv) preparation evaluation;

(v) quality assurance;

(vi) preparation recall;

(vii) packaging; and

(viii) storage of compounded preparations.

(B) Any compounded preparation with an official monograph in the USP/NF shall be compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug.

(C) Any person with an apparent illness or open lesion that may adversely affect the safety or quality of a drug product being compounded shall be excluded from direct contact with components, drug product containers, closures, any materials involved in the compounding process, and drug products until the condition is corrected.

(D) Personnel engaged in the compounding of drug preparations shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons, hair nets, gowns, hand or arm coverings, or masks shall be worn as necessary to protect personnel from chemical exposure and drug preparations from contamination.

(E) At each step of the compounding process, the pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate to conform to the formula being prepared.

(9) Quality Assurance.

(A) Initial formula validation. Prior to routine compounding of a non-sterile preparation, a pharmacy shall conduct an evaluation that shows that the pharmacy is capable of compounding a product that contains the stated amount of active ingredient(s).

(B) Finished preparation checks. The prescription drug and medication orders, written compounding procedure, preparation records, and expended materials used to make compounded non-sterile preparations shall be inspected for accuracy of correct identities and amounts of ingredients, packaging, labeling, and expected physical appearance before the non-sterile preparations are dispensed.

(10) Quality Control.

(A) The pharmacy shall follow established quality control procedures to monitor the quality of compounded drug preparations for uniformity and consistency such as capsule weight variations, adequacy of mixing, clarity, or pH of solutions. When developing these procedures, pharmacy personnel shall consider the provisions of Chapter 795, concerning Pharmacy Compounding Non-Sterile Preparations, Chapter 1075, concerning Good Compounding Practices, and Chapter 1160, concerning Pharmaceutical Calculations in Prescription Compounding contained in the current USP/NF. Such procedures shall be documented and be available for inspection.

(B) Compounding procedures that are routinely performed, including batch compounding, shall be completed and verified according to written procedures. The act of verification of a compounding procedure involves checking to ensure that calculations, weighing and measuring, order of mixing, and compounding techniques were appropriate and accurately performed.

(C) Unless otherwise indicated or appropriate, compounded preparations are to be prepared to ensure that each preparation shall contain not less than 90.0 percent and not more than 110.0 percent of the theoretically calculated and labeled quantity of active ingredient per unit weight or volume and not less than 90.0 percent and not more than 110.0 percent of the theoretically calculated weight or volume per unit of the preparation.

(e) Records.

(1) Maintenance of records. Every record required by this section shall be:

(A) kept by the pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(2) Compounding records.

(A) Compounding pursuant to patient specific prescription drug or medication orders. Compounding records for all compounded preparations shall be maintained by the pharmacy electronically or manually as part of the prescription drug or medication order, formula record, formula book, or compounding log and shall include:

(i) the date of preparation;

(ii) a complete formula, including methodology and necessary equipment which includes the brand name(s) of the raw materials, or if no brand name, the generic name(s) and name(s) of the manufacturer(s) of the raw materials and the quantities of each;

(iii) signature or initials of the pharmacist or pharmacy technician or pharmacy technician trainee performing the compounding;

(iv) signature or initials of the pharmacist responsible for supervising pharmacy technicians or pharmacy technician trainees and conducting in-process and final checks of compounded preparations if pharmacy technicians or pharmacy technician trainees perform the compounding function;

(v) the quantity in units of finished preparations or amount of raw materials;

(vi) the container used and the number of units prepared;

(vii) a reference to the location of the following documentation which may be maintained with other records, such as quality control records:

(I) the criteria used to determine the beyond-use date; and

(II) documentation of performance of quality control procedures. Documentation of the performance of quality control procedures is not required if the compounding process is done pursuant to a patient specific order and involves the mixing of two or more commercially available oral liquids or commercially available preparations when the final product is intended for external use.

(B) Compounding records when batch compounding or compounding in anticipation of future prescription drug or medication orders.

(i) Master work sheet. A master work sheet shall be developed and approved by a pharmacist for preparations prepared in batch. Once approved, a duplicate of the master work sheet shall be used as the preparation work sheet from which each batch is prepared and on which all documentation for that batch occurs. The master work sheet shall contain at a minimum:

(I) the formula;

(II) the components;

(III) the compounding directions;

(IV) a sample label;

(V) evaluation and testing requirements;

(VI) specific equipment used during preparation; and

(VII) storage requirements.

(ii) Preparation work sheet. The preparation work sheet for each batch of preparations shall document the following:

(I) identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes;

(II) lot number or each component;

(III) component manufacturer/distributor or suitable identifying number;

(IV) container specifications;

(V) unique lot or control number assigned to batch;

(VI) beyond use date of batch-prepared preparations;

(VII) date of preparation;

(VIII) name, initials, or electronic signature of the person(s) involved in the preparation;

(IX) name, initials, or electronic signature of the responsible pharmacist;

(X) finished preparation evaluation and testing specifications, if applicable; and

(XI) comparison of actual yield to anticipated or theoretical yield, when appropriate.

(f) Office Use Compounding and Distribution of Compounded Preparations to Class C Pharmacies or Veterinarians in Accordance With §563.054 of the Act.

(1) General.

(A) A pharmacy may dispense and deliver a reasonable quantity of a compounded preparation to a practitioner for office use by the practitioner in accordance with this subsection.

(B) A Class A pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute non-sterile compounded preparations to a Class C pharmacy.

(C) A Class C pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute non-sterile compounded preparations that the Class C pharmacy has compounded for other Class C pharmacies under common ownership.

(D) To dispense and deliver a compounded preparation under this subsection, a pharmacy must:

(i) verify the source of the raw materials to be used in a compounded drug;

(ii) comply with applicable United States Pharmacopoeia guidelines, including the testing requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191);

(iii) enter into a written agreement with a practitioner for the practitioner's office use of a compounded preparation;

(iv) comply with all applicable competency and accrediting standards as determined by the board; and

(v) comply with the provisions of this subsection.

(2) Written Agreement. A pharmacy that provides non-sterile compounded preparations to practitioners for office use or to another pharmacy shall enter into a written agreement with the practitioner or pharmacy. The written agreement shall:

(A) address acceptable standards of practice for a compounding pharmacy and a practitioner and receiving pharmacy that enter into the agreement including a statement that the compounded preparations may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity except as authorized by §563.054 of the Act;

(B) state that the practitioner or receiving pharmacy should include on a separate log or in a patient's chart, medication order, or medication administration record, the lot number and beyond-use date of a compounded preparation administered to a patient; and

(C) describe the scope of services to be performed by the pharmacy and practitioner or receiving pharmacy, including a statement of the process for:

(i) a patient to report an adverse reaction or submit a complaint; and

(ii) the pharmacy to recall batches of compounded preparations.

(3) Recordkeeping.

(A) Maintenance of Records.

(i) Records of orders and distribution of non-sterile compounded preparations to a practitioner for office use or to a Class C pharmacy for administration to a patient shall:

(I) be kept by the pharmacy and be available, for at least two years from the date of the record, for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies;

(II) maintained separately from the records of products dispensed pursuant to a prescription or medication order; and

(III) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy or its representative. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format. Failure to provide the records set out in this subsection, either on site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep and maintain records.

(ii) Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided the data processing system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(B) Orders. The pharmacy shall maintain a record of all non-sterile compounded preparations ordered by a practitioner for office use or by a Class C pharmacy for administration to a patient. The record shall include the following information:

(i) date of the order;

(ii) name, address, and phone number of the practitioner who ordered the preparation and if applicable, the name, address and phone number of the Class C pharmacy ordering the preparation; and

(iii) name, strength, and quantity of the preparation ordered.

(C) Distributions. The pharmacy shall maintain a record of all non-sterile compounded preparations distributed pursuant to an order to a practitioner for office use or by a Class C pharmacy for administration to a patient. The record shall include the following information:

(i) date the preparation was compounded;

(ii) date the preparation was distributed;

(iii) name, strength and quantity in each container of the preparation;

(iv) pharmacy's lot number;

(v) quantity of containers shipped; and

(vi) name, address, and phone number of the practitioner or Class C pharmacy to whom the preparation is distributed.

(D) Audit Trail.

(i) The pharmacy shall store the order and distribution records of preparations for all non-sterile compounded preparations ordered by and or distributed to a practitioner for office use or by a Class C pharmacy for administration to a patient in such a manner as to be able to provide a audit trail for all orders and distributions of any of the following during a specified time period.

(I) any strength and dosage form of a preparation (by either brand or generic name or both);

(II) any ingredient;

(III) any lot number;

(IV) any practitioner;

(V) any facility; and

(VI) any pharmacy, if applicable.

(ii) The audit trail shall contain the following information:

(I) date of order and date of the distribution;

(II) practitioner's name, address, and name of the Class C pharmacy, if applicable;

(III) name, strength and quantity of the preparation in each container of the preparation;

(IV) name and quantity of each active ingredient;

(V) quantity of containers distributed; and

(VI) pharmacy's lot number;

(4) Labeling. The pharmacy shall affix a label to the preparation containing the following information:

(A) name, address, and phone number of the compounding pharmacy;

(B) the statement: For Institutional or Office Use Only--Not for Resale; or if the preparation is distributed to a veterinarian the statement: Compounded Preparation;

(C) name and strength of the preparation or list of the active ingredients and strengths;

(D) pharmacy's lot number;

(E) beyond-use date as determined by the pharmacist using appropriate documented criteria;

(F) quantity or amount in the container;

(G) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and

(H) device-specific instructions, where appropriate.

(g) Recall Procedures.

(1) The pharmacy shall have written procedures for the recall of any compounded non-sterile preparations provided to a patient, to a practitioner for office use, or a pharmacy for administration. Written procedures shall include, but not be limited to the requirements as specified in paragraph (3) of this subsection.

(2) The pharmacy shall immediately initiate a recall of any non-sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient.

(3) In the event of a recall, the pharmacist-in-charge shall ensure that:

(A) each practitioner, facility, and/or pharmacy to which the preparation was distributed is notified, in writing, of the recall;

(B) each patient to whom the preparation was dispensed is notified, in writing, of the recall;

(C) if the preparation is prepared as a batch, the board is notified of the recall, in writing;

(D) if the preparation is distributed for office use, the Texas Department of State Health Services, Drugs and Medical Devices Group, is notified of the recall, in writing;

(E) the preparation is quarantined; and

(F) the pharmacy keeps a written record of the recall including all actions taken to notify all parties and steps taken to ensure corrective measures.

(4) If a pharmacy fails to initiate a recall, the board may require a pharmacy to initiate a recall if there is potential for or confirmed harm to a patient.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 19, 2018.

TRD-201805538
Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: February 3, 2019
For further information, please call: (512) 305-8010

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22 TAC §291.133

The Texas State Board of Pharmacy proposes amendments to §291.133, concerning Pharmacies Compounding Sterile Preparations. The amendments, if adopted, add definitions for "Active pharmaceutical ingredient," "Commercially available prod-

uct," "Easily substitutable dosage strength," and "Essentially a copy of commercially available product."

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to provide clear regulatory language by including definitions for terms used throughout the section. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendment will be in effect, Ms. Benz has determined the following:

(1) The proposed rule does not create or eliminate a government program;

(2) Implementation of the proposed rule does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed rule does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed rule does not require an increase or decrease in fees paid to the agency;

(5) The proposed rule does not create a new regulation;

(6) The proposed rule does not limit or expand an existing regulation;

(7) The proposed rule does not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed rule does not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Assistant General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., February 3, 2019.

The amendments are proposed under §§551.002, 554.051, and 562.1011 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.133. Pharmacies Compounding Sterile Preparations.

(a) Purpose. Pharmacies compounding sterile preparations, prepackaging pharmaceutical products, and distributing those products shall comply with all requirements for their specific license classification and this section. The purpose of this section is to provide standards for the:

(1) compounding of sterile preparations pursuant to a prescription or medication order for a patient from a practitioner in Class A-S, Class B, Class C-S, and Class E-S pharmacies;

(2) compounding, dispensing, and delivery of a reasonable quantity of a compounded sterile preparation in Class A-S, Class B, Class C-S, and Class E-S pharmacies to a practitioner's office for office use by the practitioner;

(3) compounding and distribution of compounded sterile preparations by a Class A-S pharmacy for a Class C-S pharmacy; and

(4) compounding of sterile preparations by a Class C-S pharmacy and the distribution of the compounded preparations to other Class C or Class C-S pharmacies under common ownership.

(b) Definitions. In addition to the definitions for specific license classifications, the following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) ACPE--Accreditation Council for Pharmacy Education.

(2) Active pharmaceutical ingredient--The substance in a drug product that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or function of the body.

(3) [~~(2)~~] Airborne particulate cleanliness class--The level of cleanliness specified by the maximum allowable number of particles per cubic meter of air as specified in the International Organization of Standardization (ISO) Classification Air Cleanliness (ISO 14644-1). For example:

(A) ISO Class 5 (formerly Class 100) is an atmospheric environment that contains less than 3,520 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 100 particles 0.5 microns in diameter per cubic foot of air);

(B) ISO Class 7 (formerly Class 10,000) is an atmospheric environment that contains less than 352,000 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 10,000 particles 0.5 microns in diameter per cubic foot of air); and

(C) ISO Class 8 (formerly Class 100,000) is an atmospheric environment that contains less than 3,520,000 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 100,000 particles 0.5 microns in diameter per cubic foot of air).

(4) [~~(3)~~] Ancillary supplies--Supplies necessary for the preparation and administration of compounded sterile preparations.

(5) [~~(4)~~] Ante-area--An ISO Class 8 or better area where personnel may perform hand hygiene and garbing procedures, staging of components, order entry, labeling, and other high-particulate generating activities. It is also a transition area that:

(A) provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas; and

(B) reduces the need for the heating, ventilating and air conditioning (HVAC) control system to respond to large disturbances.

(6) [~~(5)~~] Aseptic Processing--A mode of processing pharmaceutical and medical preparations that involves the separate sterilization of the preparation and of the package (containers-closures or packaging material for medical devices) and the transfer of the preparation into the container and its closure under at least ISO Class 5 conditions.

(7) [~~(6)~~] Automated compounding device--An automated device that compounds, measures, and/or packages a specified quantity of individual components in a predetermined sequence for a designated sterile preparation.

(8) [~~(7)~~] Batch--A specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced during a single preparation cycle.

(9) [~~(8)~~] Batch preparation compounding--Compounding of multiple sterile preparation units, in a single discrete process, by the same individual(s), carried out during one limited time period. Batch preparation/compounding does not include the preparation of multiple sterile preparation units pursuant to patient specific medication orders.

(10) [~~(9)~~] Beyond-use date--The date or time after which the compounded sterile preparation shall not be stored or transported or begin to be administered to a patient. The beyond-use date is determined from the date or time the preparation is compounded.

(11) [~~(10)~~] Biological Safety Cabinet, Class II--A ventilated cabinet for personnel, product or preparation, and environmental protection having an open front with inward airflow for personnel protection, downward HEPA filtered laminar airflow for product protection, and HEPA filtered exhausted air for environmental protection.

(12) [~~(11)~~] Buffer Area--An ISO Class 7 or, if a Class B pharmacy, ISO Class 8 or better, area where the primary engineering control area is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding sterile preparations.

(13) [~~(12)~~] Clean room--A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.

(14) Commercially available product--A drug product that is a marketed drug product or available on the market, and subject to federal requirements relating to approval, labeling, and Current Good Manufacturing Practice (CGMP) requirements, the federal copies restrictions under section 503A of the Federal Food Drug and Cosmetic Act, and the copy restrictions described under subsections (d)(1)(C) and (D) of this section.

(15) [~~(13)~~] Component--Any ingredient intended for use in the compounding of a drug preparation, including those that may not appear in such preparation.

(16) [~~(14)~~] Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or device:

(A) as the result of a practitioner's prescription drug or medication order based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(B) for administration to a patient by a practitioner as the result of a practitioner's initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(C) in anticipation of prescription drug or medication orders based on routine, regularly observed prescribing patterns; or

(D) for or as an incident to research, teaching, or chemical analysis and not for sale or dispensing, except as allowed under §562.154 or Chapter 563 of the Occupations Code.

(17) [~~(15)~~] Compounding Aseptic Isolator--A form of barrier isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment shall not occur unless it has first passed through a microbial retentive filter (HEPA minimum).

(18) [~~(16)~~] Compounding Aseptic Containment Isolator--A compounding aseptic isolator designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.

(19) [~~(17)~~] Compounding Personnel--A pharmacist, pharmacy technician, or pharmacy technician trainee who performs the actual compounding; a pharmacist who supervises pharmacy technicians or pharmacy technician trainees compounding sterile preparations, and a pharmacist who performs an intermediate or final verification of a compounded sterile preparation.

(20) [~~(18)~~] Critical Area--An ISO Class 5 environment.

(21) [~~(19)~~] Critical Sites--A location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampules, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination. Risk of microbial particulate contamination of the critical site increases with the size of the openings and exposure time.

(22) [~~(20)~~] Device--An instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent, or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed by a practitioner.

(23) [~~(21)~~] Direct Compounding Area--A critical area within the ISO Class 5 primary engineering control where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.

(24) [~~(22)~~] Disinfectant--An agent that frees from infection, usually a chemical agent but sometimes a physical one, and that destroys disease-causing pathogens or other harmful microorganisms but may not kill bacterial and fungal spores. It refers to substances applied to inanimate objects.

(25) Easily substitutable dosage strength--The dosage strength of a compounded drug preparation that can be achieved by the administration of fractional or multiple doses of a commercially available drug product.

(26) Essentially a copy of a commercially available product--A compounded preparation:

(A) that has the same active pharmaceutical ingredient(s) as the commercially available drug product;

(B) containing an active pharmaceutical ingredient that has:

(i) the same or similar dosage strength; or

(ii) an easily substitutable dosage strength; and

(C) for which the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug preparation.

(27) [~~(23)~~] First Air--The air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

(28) [~~(24)~~] Hazardous Drugs--Drugs that, studies in animals or humans indicate exposure to the drugs, have a potential for causing cancer, development or reproductive toxicity, or harm to or-

gans. For the purposes of this chapter, radiopharmaceuticals are not considered hazardous drugs.

(29) [~~(25)~~] Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of 105 degrees F (41 degrees C).

(30) [~~(26)~~] HVAC--Heating, ventilation, and air conditioning.

(31) [~~(27)~~] Immediate use--A sterile preparation that is not prepared according to USP 797 standards (i.e., outside the pharmacy and most likely not by pharmacy personnel) which shall be stored for no longer than one hour after completion of the preparation.

(32) [~~(28)~~] IPA--Isopropyl alcohol (2-propanol).

(33) [~~(29)~~] Labeling--All labels and other written, printed, or graphic matter on an immediate container of an article or preparation or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term "label" designates that part of the labeling on the immediate container.

(34) [~~(30)~~] Media-Fill Test--A test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile preparation without microbial contamination. During this test, a microbiological growth medium such as Soybean-Casein Digest Medium is substituted for the actual drug preparation to simulate admixture compounding. The issues to consider in the development of a media-fill test are the following: media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required.

(35) [~~(31)~~] Multiple-Dose Container--A multiple-unit container for articles or preparations intended for potential administration only and usually contains antimicrobial preservatives. The beyond-use date for an opened or entered (e.g., needle-punctured) multiple-dose container with antimicrobial preservatives is 28 days, unless otherwise specified by the manufacturer.

(36) [~~(32)~~] Negative Pressure Room--A room that is at a lower pressure compared to adjacent spaces and, therefore, the net flow of air is into the room.

(37) [~~(33)~~] Office use--The administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy in accordance with Chapter 562 of the Act, or for administration or provision by a veterinarian in accordance with §563.054 of the Act.

(38) [~~(34)~~] Pharmacy Bulk Package--A container of a sterile preparation for potential use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes. The closure shall be penetrated only one time after constitution with a suitable sterile transfer device or dispensing set, which allows measured dispensing of the contents. The pharmacy bulk package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).

(39) [~~(35)~~] Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original container into unit dose packaging or a multiple dose container for distribution within a facility licensed as a Class C pharmacy or to other pharmacies under common ownership for distribution within those facilities. The term as defined does not prohibit the prepackaging of drug products for use within other pharmacy classes.

(40) [~~(36)~~] Preparation or Compounded Sterile Preparation--A sterile admixture compounded in a licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed prescriber. The components of the preparation may or may not be sterile products.

(41) [~~(37)~~] Primary Engineering Control--A device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding sterile preparations. Such devices include, but may not be limited to, laminar airflow workbenches, biological safety cabinets, compounding aseptic isolators, and compounding aseptic containment isolators.

(42) [~~(38)~~] Product--A commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the U.S. Food and Drug Administration (FDA). Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer's labeling or product package insert.

(43) [~~(39)~~] Positive Control--A quality assurance sample prepared to test positive for microbial growth.

(44) [~~(40)~~] Quality assurance--The set of activities used to ensure that the process used in the preparation of sterile drug preparations lead to preparations that meet predetermined standards of quality.

(45) [~~(41)~~] Quality control--The set of testing activities used to determine that the ingredients, components (e.g., containers), and final compounded sterile preparations prepared meet predetermined requirements with respect to identity, purity, non-pyrogenicity, and sterility.

(46) [~~(42)~~] Reasonable quantity--An amount of a compounded drug that:

(A) does not exceed the amount a practitioner anticipates may be used in the practitioner's office or facility before the beyond use date of the drug;

(B) is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice; and

(C) for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.

(47) [~~(43)~~] Segregated Compounding Area--A designated space, either a demarcated area or room, that is restricted to preparing low-risk level compounded sterile preparations with 12-hour or less beyond-use date. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of compounded sterile preparations and shall be void of activities and materials that are extraneous to sterile compounding.

(48) [~~(44)~~] Single-dose container--A single-unit container for articles or preparations intended for parenteral administration only. It is intended for a single use. A single-dose container is labeled as such. Examples of single-dose containers include pre-filled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.

(49) [~~(45)~~] SOPs--Standard operating procedures.

(50) [~~(46)~~] Sterilizing Grade Membranes--Membranes that are documented to retain 100% of a culture of 107 microorganisms of a strain of Brevundimonas (Pseudomonas) diminuta per square centimeter of membrane surface under a pressure of not less than 30 psi (2.0 bar). Such filter membranes are nominally at 0.22-micrometer or

0.2-micrometer nominal pore size, depending on the manufacturer's practice.

(51) [~~(47)~~] Sterilization by Filtration--Passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent.

(52) [~~(48)~~] Terminal Sterilization--The application of a lethal process, e.g., steam under pressure or autoclaving, to sealed final preparation containers for the purpose of achieving a predetermined sterility assurance level of usually less than 10-6 or a probability of less than one in one million of a non-sterile unit.

(53) [~~(49)~~] Unidirectional Flow--An airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.

(54) [~~(50)~~] USP/NF--The current edition of the United States Pharmacopeia/National Formulary.

(c) - (g) No change.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 19, 2018.

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Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: February 3, 2019
For further information, please call: (512) 305-8010

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SUBCHAPTER H. OTHER CLASSES OF PHARMACY

22 TAC §291.153

The Texas State Board of Pharmacy proposes amendments to §291.153, concerning Central Prescription Drug or Medication Order Processing Pharmacy (Class G). The amendments, if adopted, provide for the provision of medication therapy management services in Class G pharmacies and update a reference to pharmacy technician certification.

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to allow Class G pharmacies to provide medication therapy management services to patients, which will increase patient access to comprehensive, patient-specific pharmaceutical care services. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendment will be in effect, Ms. Benz has determined the following:

(1) The proposed rule does not create or eliminate a government program;

(2) Implementation of the proposed rule does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed rule does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed rule does not require an increase or decrease in fees paid to the agency;

(5) The proposed rule does not create a new regulation;

(6) The proposed rule expands an existing regulation;

(7) The proposed rule does not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed rule may positively affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Assistant General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., February 3, 2019.

The amendments are proposed under §§551.002, 554.051, and 562.1011 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.153. Central Prescription Drug or Medication Order Processing Pharmacy (Class G).

(a) Purpose.

(1) The purpose of this section is to provide standards for a centralized prescription drug or medication order processing pharmacy, including a pharmacy that provides medication therapy management services in accordance with the requirements of this section.

(2) Any facility established for the primary purpose of processing prescription drug or medication drug orders or conducting medication therapy management services shall be licensed as a Class G pharmacy under the Act. A Class G pharmacy shall not store bulk drugs, or dispense a prescription drug order. Nothing in this subsection shall prohibit an individual pharmacist employee who is licensed in Texas from remotely accessing the pharmacy's electronic data base from a location other than a licensed pharmacy in order to process prescription or medication drug orders, provided the pharmacy establishes controls to protect the privacy and security of confidential records, and the Texas-licensed pharmacist does not engage in the receiving of written prescription or medication orders or the maintenance of prescription or medication drug orders at the non-licensed remote location.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in the Act.

(1) Centralized prescription drug or medication order processing--The processing of a prescription drug or medication orders by a Class G pharmacy on behalf of another pharmacy, a health care provider, or a payor. Centralized prescription drug or medication order

processing does not include the dispensing of a prescription drug but includes any of the following:

(A) receiving, interpreting, or clarifying prescription drug or medication drug orders;

(B) data entering and transferring of prescription drug or medication order information;

(C) performing drug regimen review;

(D) obtaining refill and substitution authorizations;

(E) verifying accurate prescription data entry;

(F) interpreting clinical data for prior authorization for dispensing;

(G) performing therapeutic interventions; and

(H) providing drug information concerning a patient's prescription.

(2) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or, if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.

(3) Medication Therapy Management (MTM) Services--Pharmaceutical care services that are independent of, but may occur in conjunction with, the dispensing of a drug or device, and are provided by a pharmacist to optimize therapeutic outcomes for individual patients. MTM services do not include drug therapy management under §295.13 of this title. MTM services include, but are not limited to, the following patient-specific activities delivered in an interaction between the patient and the pharmacist:

(A) identifying and resolving barriers regarding the patient's access to medication;

(B) identifying and resolving barriers regarding the patient's medication adherence;

(C) coordination of the patient's medication therapy to improve continuity of care, especially when prescribed multiple medications from multiple practitioners, or for multiple disease states or conditions, including effective communication with prescribers to develop a uniform plan of care;

(D) performing a comprehensive medication therapy review at each patient encounter to determine the effectiveness of the patient's medication and evaluate any drug-related problems or adverse drug events;

(E) providing education, counseling, or training to the patient or patient's caregiver to understanding of health conditions and appropriate medication use;

(F) formulating medication treatment plans for the patient;

(G) performing follow-up procedures to monitor and evaluate the patient's response to medication therapy, safety and effectiveness;

(H) documenting the patient's MTM session; and

(I) providing an individualized documentation of the MTM session to the patient or patient's caregiver.

(c) Personnel.

(1) Pharmacist-in-charge.

(A) General. Each Class G pharmacy shall have one pharmacist-in-charge who is employed on a full-time basis, who may be the pharmacist-in-charge for only one such pharmacy.

(B) Responsibilities. The pharmacist-in-charge shall have responsibility for the practice of pharmacy at the pharmacy for which he or she is the pharmacist-in-charge. The pharmacist-in-charge may advise the owner on administrative or operational concerns. The pharmacist-in-charge shall have responsibility for, at a minimum, the following:

(i) educating and training pharmacy technicians and pharmacy technician trainees;

(ii) maintaining records of all transactions of the Class G pharmacy required by applicable state and federal laws and sections;

(iii) adhering to policies and procedures regarding the maintenance of records in a data processing system such that the data processing system is in compliance with Class G pharmacy requirements; and

(iv) legally operating the pharmacy, including meeting all inspection and other requirements of all state and federal laws or sections governing the practice of pharmacy.

(2) Owner. The owner of a Class G pharmacy shall have responsibility for all administrative and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on administrative and operational concerns. The owner shall have responsibility for, at a minimum, the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with the pharmacist-in-charge or another Texas licensed pharmacist:

(A) providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice; and

(B) establishing policies and procedures regarding maintenance, storage, and retrieval of records in a data processing system such that the system is in compliance with state and federal requirements.

(3) Pharmacists.

(A) General.

(i) The pharmacist-in-charge shall be assisted by sufficient number of additional licensed pharmacists as may be required to operate the Class G pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.

(ii) All pharmacists shall assist the pharmacist-in-charge in meeting his or her responsibilities.

(iii) Pharmacists are solely responsible for the direct supervision of pharmacy technicians and pharmacy technician trainees and for designating and delegating duties, other than those listed in subparagraph (B) of this paragraph, to pharmacy technicians and pharmacy technician trainees. Each pharmacist shall be responsible for any delegated act performed by pharmacy technicians and pharmacy technician trainees under his or her supervision.

(iv) Pharmacists shall directly supervise pharmacy technicians and pharmacy technician trainees who are entering prescription data into the pharmacy's data processing system by one of the following methods.

(I) Physically present supervision. A pharmacist shall be physically present to directly supervise a pharmacy technician or pharmacy technician trainee who is entering prescription order or

medication order data into the data processing system. Each prescription or medication order entered into the data processing system shall be verified at the time of data entry.

(II) Electronic supervision. A pharmacist may electronically supervise a pharmacy technician or pharmacy technician trainee who is entering prescription order or medication order data into the data processing system provided the pharmacist:

(-a-) is on-site, in the pharmacy where the technician/trainee is located;

(-b-) has immediate access to any original document containing prescription or medication order information or other information related to the dispensing of the prescription or medication order. Such access may be through imaging technology provided the pharmacist has the ability to review the original, hardcopy documents if needed for clarification; and

(-c-) verifies the accuracy of the data entered information prior to the release of the information to the system for storage.

(III) Electronic verification of data entry by pharmacy technicians or pharmacy technician trainees. A pharmacist may electronically verify the data entry of prescription information into a data processing system provided:

(-a-) a pharmacist is on-site in the pharmacy where the pharmacy technicians/trainees are located;

(-b-) the pharmacist electronically conducting the verification is either a:

(-1-) Texas licensed pharmacist; or

(-2-) pharmacist employed by a Class E pharmacy that has the same owner as the Class G pharmacy where the pharmacy technicians/trainees are located or that has entered into a written contract or agreement with the Class G pharmacy, which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations;

(-c-) the pharmacy establishes controls to protect the privacy and security of confidential records; and

(-d-) the pharmacy keeps permanent records of prescriptions electronically verified for a period of two years.

(v) All pharmacists while on duty, shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(B) Duties. Duties which may only be performed by a pharmacist are as follows:

(i) receiving oral prescription drug or medication orders and reducing these orders to writing, either manually or electronically;

(ii) interpreting prescription drug or medication orders;

(iii) selecting drug products;

(iv) verifying the data entry of the prescription drug or medication order information at the time of data entry prior to the release of the information to a Class A, Class C, or Class E pharmacy for dispensing;

(v) communicating to the patient or patient's agent information about the prescription drug or device which in the exercise of the pharmacist's professional judgment, the pharmacist deems significant, as specified in §291.33(c) of this title (relating to Operational Standards);

(vi) communicating to the patient or the patient's agent on his or her request information concerning any prescription drugs dispensed to the patient by the pharmacy;

(vii) assuring that a reasonable effort is made to obtain, record, and maintain patient medication records; and

(viii) interpreting patient medication records and performing drug regimen reviews, including the provision of medication therapy management services.

(4) Pharmacy Technicians and Pharmacy Technician Trainees.

(A) General. All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

(B) Duties.

(i) Pharmacy technicians and pharmacy technician trainees may not perform any of the duties listed in paragraph (3)(B) of this subsection.

(ii) A pharmacist may delegate to pharmacy technicians and pharmacy technician trainees any nonjudgmental technical duty associated with the preparation and distribution of prescription drugs provided:

(I) a pharmacist verifies the accuracy of all acts, tasks, and functions performed by pharmacy technicians and pharmacy technician trainees;

(II) pharmacy technicians and pharmacy technician trainees are under the direct supervision of and responsible to a pharmacist; and

(iii) Pharmacy technicians and pharmacy technician trainees may perform only nonjudgmental technical duties associated with the preparation of prescription drugs, as follows:

(I) initiating and receiving refill authorization requests; and

(II) entering prescription or medication order data into a data processing system.

(C) Ratio of on-site pharmacists to pharmacy technicians and pharmacy technician trainees. A Class G pharmacy may have a ratio of on-site pharmacists to pharmacy technicians and pharmacy technician trainees of 1:8 provided:

(i) at least seven are pharmacy technicians and not pharmacy technician trainees; and

(ii) the pharmacy has written policies and procedures regarding the supervision of pharmacy technicians and pharmacy technician trainees.

(5) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows.

(A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician, or a certified pharmacy technician, if the technician maintains current certification by an [~~with the Pharmacy Technician Certification Board or any other~~] entity providing a pharmacy technician certification [~~an~~] examination approved by the board.

(B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an identification tag or badge that bears

the person's name and identifies him or her as a pharmacy technician trainee.

(C) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist intern.

(D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist.

(d) Operational Standards.

(1) General requirements.

(A) A Class A, Class C, or Class E Pharmacy may outsource prescription drug or medication order processing to a Class G pharmacy provided the pharmacies:

(i) have:

(I) the same owner; or

(II) entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations; and

(ii) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to perform a non-dispensing function.

(B) A Class G pharmacy shall comply with the provisions applicable to the class of pharmacy contained in either §§291.31 - 291.35 of this title (relating to Definitions, Personnel, Operational Standards, Records, and Official Prescription Requirements in Class A (Community) Pharmacies), or §§291.72 - 291.75 of this title (relating to Definitions, Personnel, Operational Standards, and Records in a Class C (Institutional) Pharmacy), or §§291.102 - 291.105 of this title (relating to Definitions, Personnel, Operational Standards, and Records in a Class E (Non-Resident) Pharmacy) to the extent applicable for the specific processing activity and this section including:

(i) duties which must be performed by a pharmacist; and

(ii) supervision requirements for pharmacy technicians and pharmacy technician trainees.

(2) Licensing requirements.

(A) A Class G pharmacy shall register with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application).

(B) A Class G pharmacy which changes ownership shall notify the board within 10 days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications).

(C) A Class G pharmacy which changes location and/or name shall notify the board of the change within 10 days and file for an amended license as specified in §291.3 of this title.

(D) A Class G pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within 10 days of the change, following the procedures in §291.3 of this title.

(E) A Class G pharmacy shall notify the board in writing within 10 days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

(F) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for issuance and renewal of a license and the issuance of an amended license.

(G) A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.

(3) Environment.

(A) General requirements.

(i) The pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be in good operating condition.

(ii) The pharmacy shall be properly lighted and ventilated.

(B) Security.

(i) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of prescription drug records.

(ii) Pharmacies shall employ appropriate measures to ensure that security of prescription drug records is maintained at all times to prohibit unauthorized access.

(4) Policy and Procedures. A policy and procedure manual shall be maintained by the Class G pharmacy and be available for inspection. The manual shall:

(A) outline the responsibilities of each of the pharmacies;

(B) include a list of the name, address, telephone numbers, and all license/registration numbers of the pharmacies involved in centralized prescription drug or medication order processing; and

(C) include policies and procedures for:

(i) protecting the confidentiality and integrity of patient information;

(ii) maintaining appropriate records to identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist or pharmacy technician who performed any processing;

(iii) complying with federal and state laws and regulations;

(iv) operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; and

(v) annually reviewing the written policies and procedures and documenting such review.

(e) Records.

(1) every record required to be kept under the provisions of this section shall be:

(A) kept by the pharmacy and be available, for at least two years from the date of such inventory or record, for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy.

If the pharmacy maintains the records in an electronic format, the requested records must be provided in a mutually agreeable electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(2) A Class G pharmacy that processes prescription drug orders or medication drug orders [~~The pharmacy~~] shall maintain appropriate records which identify, by prescription drug or medication order, the name(s), initials, or identification code(s) of each pharmacist, pharmacy technician, or pharmacy technician trainee who performs a processing function for a prescription drug or medication order. Such records may be maintained:

(A) separately by each pharmacy and pharmacist; or

(B) in a common electronic file as long as the records are maintained in such a manner that the data processing system can produce a printout which lists the functions performed by each pharmacy and pharmacist.

(3) In addition, the pharmacy shall comply with the record keeping requirements applicable to the class of pharmacy to the extent applicable for the specific processing activity and this section.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 19, 2018.

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Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director
Texas State Board of Pharmacy
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For further information, please call: (512) 305-8010

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CHAPTER 315. CONTROLLED SUBSTANCES

22 TAC §315.12

The Texas State Board of Pharmacy proposes amendments to §315.12, concerning Schedule III through V Prescription Forms. The amendments, if adopted, correct a reference to the agency responsible for issuing a controlled substances registration number to the United States Drug Enforcement Administration.

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to provide accurate regulatory language by correcting an agency reference. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendment will be in effect, Ms. Benz has determined the following:

(1) The proposed rule does not create or eliminate a government program;

(2) Implementation of the proposed rule does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed rule does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed rule does not require an increase or decrease in fees paid to the agency;

(5) The proposed rule does not create a new regulation;

(6) The proposed rule does limit or expand an existing regulation;

(7) The proposed rule does not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed rule does not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Assistant General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., February 3, 2019.

The amendments are proposed under §§551.002, 554.051, and 562.1011 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§315.12. Schedule III through V Prescription Forms[- ~~Effective September 1, 2016~~].

(a) A practitioner, as defined in the TCSA, §481.002(39)(A), (C), and (D), may use prescription forms ordered through individual sources or through an electronic prescription that includes the controlled substances registration number issued by the United States Drug Enforcement Administration [~~board~~] and meets all requirements of the TCSA.

(b) If a written prescription form is to be used to prescribe a controlled substance the dispensing practitioner must be registered with the DEA under both state and federal law to prescribe controlled substances.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 19, 2018.

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Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director
Texas State Board of Pharmacy
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For further information, please call: (512) 305-8010

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TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 703. GRANTS FOR CANCER PREVENTION AND RESEARCH

25 TAC §§703.3, 703.13, 703.21, 703.22

The Cancer Prevention and Research Institute of Texas (CPRIT or the Institute) proposes amendments to 25 Texas Administrative Code §§703.3, 703.13, 703.21, and 703.22. The proposed amendments clarify the processes, annual training, audit deadlines, and reporting periods for Institute grant recipients.

Background and Justification

The proposed amendment to §703.3 provides the process for a product development research grant applicant to receive a refund of the application fee if the CPRIT or the grant applicant withdraws the proposal from the review process prior to an evaluation by peer reviewers. The changes to §703.13 clarify the deadline for grantees to submit the required audit report, revising the deadline from 270 days to nine months after the close of the grantee's fiscal year. The proposed amendment to §703.21 sets the initial reporting period for prevention grants approved for an award during the last quarter of the state fiscal year. The proposed change allows prevention grantees to report on a full initial quarter. The proposed amendment to §703.22 changes the deadline for grant recipients to complete annual compliance training from November 1 to December 31. The change correlates the annual requirement to the calendar year.

Fiscal Note

Kristen Pauling Doyle, Deputy Executive Officer and General Counsel for the Cancer Prevention and Research Institute of Texas, has determined that for the first five-year period the rule changes are in effect, there will be no foreseeable implications relating to costs or revenues for state or local government due to enforcing or administering the rules.

Public Benefit and Costs

Ms. Doyle has determined that for each year of the first five years the rule changes are in effect the public benefit anticipated due to enforcing the rule will be clarifying processes, deadlines, and reporting periods for grant recipients.

Small Business, Micro-Business, and Rural Communities Impact Analysis

Ms. Doyle has determined that the rule changes will not affect small businesses, micro businesses, or rural communities.

Government Growth Impact Statement

The Institute, in accordance with 34 Texas Administrative Code §11.1, has determined that during the first five years that the proposed rule changes will be in effect:

(1) the proposed rule changes will not create or eliminate a government program;

(2) implementation of the proposed rule changes will not affect the number of employee positions;

(3) implementation of the proposed rule changes will not require an increase or decrease in future legislative appropriations;

(4) the proposed rule changes will not affect fees paid to the agency;

(5) the proposed rule changes will not create new rules;

(6) the proposed rule changes will not expand existing rules;

(7) the proposed rule changes will not change the number of individuals subject to the rules; and

(8) The rule changes are unlikely to have a significant impact on the state's economy. Although these changes are likely to have neutral impact on the state's economy, the Institute lacks sufficient data to predict the impact with certainty.

Submit written comments on the proposed rule changes to Ms. Kristen Pauling Doyle, General Counsel, Cancer Prevention and Research Institute of Texas, P.O. Box 12097, Austin, Texas 78711, no later than February 4, 2019. The Institute asks parties filing comments to indicate whether they support the rule revisions proposed by the Institute and, if a change is requested, to provide specific text proposed to be included in the rule. Comments may be submitted electronically to kdoyle@cprit.texas.gov. Comments may be submitted by facsimile transmission to (512) 475-2563.

Statutory Authority

The Institute proposes the rule changes under the authority of the Texas Health and Safety Code Annotated, §102.108, which provides the Institute with broad rule-making authority to administer the chapter. Ms. Doyle has reviewed the proposed amendments and certifies the proposal to be within the Institute's authority to adopt.

There is no other statute, article, or code affected by these rules.

§703.3. Grant Applications.

(a) The Institute shall accept Grant Applications for Cancer Research and Cancer Prevention programs to be funded by the Cancer Prevention and Research Fund or the proceeds of general obligation bonds issued on behalf of the Institute in response to standard format Requests for Applications issued by the Institute.

(b) Each Request for Applications shall be publicly available through the Institute's Internet website. The Institute reserves the right to modify the format and content requirements for the Requests for Applications from time to time. Notice of modifications will be announced and available through the Institute's Internet website. The Request for Applications shall:

(1) Include guidelines for the proposed projects and may be accompanied by instructions provided by the Institute.

(2) State the criteria to be used during the Grant Review Process to evaluate the merit of the Grant Application, including guidance regarding the range of possible scores.

(A) The specific criteria and scoring guidance shall be developed by the Chief Program Officer in consultation with the Review Council.

(B) When the Institute will use a preliminary evaluation process as described in §703.6 of this chapter (relating to Grant [~~Grants~~] Review Process) for the Grant Applications submitted pursuant to a particular Grant Mechanism, the Request for Applications shall state the criteria and Grant Application components to be included in the preliminary evaluation.

(3) Specify limits, if any, on the number of Grant Applications that may be submitted by an entity for a particular Grant Mechanism to ensure timely and high-quality review when a large number of Grant Applications are anticipated.

(c) Requests for Applications for Cancer Research and Cancer Prevention projects issued by the Institute may address, but are not limited to, the following areas:

(1) Basic research;

(2) Translational research, including proof of concept, preclinical, and Product Development activities;

(3) Clinical research;

(4) Population based research;

(5) Training;

(6) Recruitment to the state of researchers and clinicians with innovative Cancer Research approaches;

(7) Infrastructure, including centers, core facilities, and shared instrumentation;

(8) Implementation of the Texas Cancer Plan; and

(9) Evidence based Cancer Prevention education, outreach, and training, and clinical programs and services.

(d) An otherwise qualified applicant is eligible solely for the Grant Mechanism specified by the Request for Applications under which the Grant Application was submitted.

(e) The Institute may limit the number of times a Grant Application not recommended for a Grant Award during a previous Grant Review Cycle may be resubmitted in a subsequent Grant Review Cycle. The Request for Applications will state the resubmission guidelines, including specific instructions for resubmissions.

(f) Failure to comply with the material and substantive requirements set forth in the Request for Applications may serve as grounds for disqualification from further consideration of the Grant Application by the Institute. A Grant Application determined by the Institute to be incomplete or otherwise noncompliant with the terms or instructions set forth by the Request for Applications shall not be eligible for consideration of a Grant Award.

(g) Only those Grant Applications submitted via the designated electronic portal designated by the Institute by the deadline, if any, stated in the Request for Applications shall be eligible for consideration of a Grant Award.

(1) Nothing herein shall prohibit the Institute from extending the submission deadline for one or more Grant Applications upon a showing of good cause, as determined by the Chief Program Officer.

(2) A request to extend the Grant Application submission deadline must be in writing and sent to the CPRIT Helpdesk via electronic mail, within 24 hours of the submission deadline.

(3) The Institute shall document any deadline extension granted, including the good cause for extending the deadline and will cause the documentation to be maintained as part of the Grant Review Process records.

(h) The Grant Applicant shall certify that it has not made and will not make a donation to the Institute or any foundation created to benefit the Institute.

(1) Grant Applicants that make a donation to the Institute or any foundation created to benefit the Institute on or after June 14, 2013, are ineligible to be considered for a Grant Award.

(2) For purposes of the required certification, the Grant Applicant includes the following individuals or the spouse or dependent child(ren) of the following individuals:

(A) the Principal Investigator, Program Director, or Company Representative;

(B) a Senior Member or Key Personnel listed on the Grant Application; and

(C) an officer or director of the Grant Applicant.

(3) Notwithstanding the foregoing, one or more donations exceeding $500 by an employee of a Grant Applicant not described by paragraph (2) of this subsection shall be considered to be made on behalf of the Grant Applicant for purposes of the certification.

(4) The certification shall be made at the time the Grant Application is submitted.

(5) The Chief Compliance Officer shall compare the list of Grant Applicants to a current list of donors to the Institute and any foundation created to benefit the Institute.

(6) To the extent that the Chief Compliance Officer has reason to believe that a Grant Applicant has made a donation to the Institute or any foundation created to benefit the Institute, the Chief Compliance Officer shall seek information from the Grant Applicant to resolve any issue. The Grant Application may continue in the Grant Review Process during the time the additional information is sought and under review by the Institute.

(7) If the Chief Compliance Officer determines that the Grant Applicant has made a donation to the Institute or any foundation created to benefit the Institute, then the Institute shall take appropriate action. Appropriate action may entail:

(A) Withdrawal of the Grant Application from further consideration; or

(B) Return of the donation, if the return of the donation is possible without impairing Institute operations.

(8) If the donation is returned to the Applicant, then the Grant Application is eligible to be considered for a Grant Award.

(i) Grant Applicants shall identify by name all sources of funding contributing to the project proposed for a Grant Award. A Grant Applicant for a Product Development Research Grant Award must provide a capitalization table that includes those individuals or entities that have an investment, stock or rights in the company. The Institute shall make the information provided by the Grant Applicant available to Scientific Research and Prevention Programs Committee members, Institute employees, independent contractors participating in the Grant Review Process, Program Integration Committee Members and Oversight Committee Members for purposes of identifying potential Conflicts of Interest prior to reviewing or taking action on the Grant Application. The information shall be maintained in the Institute's Grant Review Process records.

(j) A Grant Applicant shall indicate if the Grant Applicant is currently ineligible to receive Federal or State grant funds due to debarment or suspension or if the Grant Applicant has had a grant terminated for cause within five years prior to the submission date of the Grant Application. For purposes of the provision, the term Grant Applicant includes the personnel, including collaborators or contractors, who will be working on the Grant Award. A Grant Applicant is not eligible to receive a Grant Award if the Grant Applicant is debarred, suspended, ineligible or otherwise excluded from participation in a federal or state grant award.

(k) The Institute may require each Grant Applicant for a Cancer Research Grant Award for Product Development to submit an application fee.

(1) The Chief Executive Officer shall adopt a policy regarding the application fee amount.

(2) The Institute shall use the application fee amounts to defray the Institute's costs associated with the Product Development review processes, including due diligence and intellectual property reviews, as specified in the Request for Application.

(3) Unless a request to submit the fee after the deadline has been approved by the Institute, the Institute may administratively withdraw a Grant Application if the application review fee is not received by the Institute within seven business days of the Grant Application submission deadline.

(4) Upon a written request from the Grant Applicant, the Institute may refund the application fee to the Grant Applicant if the Grant Applicant withdraws the Grant Application or the Grant Application is otherwise removed from the Grant Review Process prior to the review of the Grant Application by the Scientific Research and Prevention Programs Committees. The Institute's decision regarding return of the application fee is final.

(l) During the course of administrative review of the Grant Application, the Institute may contact the Grant Applicant to seek clarification on information provided in the Grant Application or to request additional information if such information clarifies the Grant Application. The Institute shall keep a record of requests made under this subsection for review by the Chief Compliance Officer.

§703.13. Audits and Investigations.

(a) Upon request and with reasonable notice, an entity receiving Grant Award funds directly under the Grant Contract or indirectly through a subcontract under the Grant Contract shall allow, or shall cause the entity that is maintaining such items to allow the Institute, or auditors or investigators working on behalf of the Institute, including the State Auditor and/or the Comptroller of Public Accounts for the State of Texas, to review, inspect, audit, copy or abstract its records pertaining to the specific Grant Contract during the term of the Grant Contract and for the three year period following the date the last disbursement of funds is made by the Institute or all reports required pursuant to the Grant Contract are submitted and approved, whichever date is later.

(1) A Grant Recipient shall maintain its records pertaining to the specific Grant Contract for a period of three years following the date the last disbursement of funds is made by the Institute or all reports required pursuant to the Grant Contract are submitted and approved, whichever date is later.

(2) The Grant Recipient may maintain its records in either electronic or paper format.

(b) Notwithstanding the foregoing, the Grant Recipient shall submit a single audit determination form no later than 60 days following the close of the Grant Recipient's fiscal year. The Grant Recipient shall report whether the Grant Recipient has expended $750,000 or more in state awards during the Grant Recipient's fiscal year. If the Grant Recipient has expended $750,000 or more in state awards in its fiscal year, the Grant Recipient shall obtain either an annual single independent audit, a program specific independent audit, or an agreed upon procedures engagement as defined by the American Institute of Certified Public Accountants and pursuant to guidance provided in subsection (e) of this section.

(1) The audited time period is the Grant Recipient's fiscal year.

(2) The audit must be submitted to the Institute within thirty (30) days of receipt by the Grant Recipient but no later than nine (9) months [~~270 days~~] following the close of the Grant Recipient's fiscal year and shall include a corrective action plan that addresses any weaknesses, deficiencies, wrongdoings, or other concerns raised by the audit report and a summary of the action taken by the Grant Recipient to address the concerns, if any, raised by the audit report.

(A) The Grant Recipient may seek additional time to submit the required audit and corrective action plan by providing a written explanation for its failure to timely comply and providing an expected time for the submission.

(B) The Grant Recipient's request for additional time must be submitted on or before the due date of the required audit and corrective action plan. For purposes of this rule, the "due date of the required audit" is no later than nine (9) months [~~the 270th day~~] following the close of the Grant Recipient's fiscal year.

(C) Approval of the Grant Recipient's request for additional time is at the discretion of the Institute. Such approval must be granted by the Chief Executive Officer.

(c) No reimbursements or advances of Grant Award funds shall be made to the Grant Recipient if the Grant Recipient is delinquent in filing the required audit and corrective action plan. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may receive reimbursements or advances of Grant Award funds during the pendency of the delinquency unless the Institute's approval declines to permit reimbursements or advances of Grant Award funds until the delinquency is addressed.

(d) A Grant Recipient that is delinquent in submitting to the Institute the audit and corrective action plan required by this section is not eligible to be awarded a new Grant Award or a continuation Grant Award until the required audit and corrective action plan are submitted. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may remain eligible to be awarded a new Grant Award or a continuation Grant Award unless the Institute's approval declines to continue eligibility during the pendency of the delinquency.

(e) For purposes of this rule, an agreed upon procedures engagement is one in which an independent certified public accountant is hired by the Grant Recipient to issue a report of findings based on specific procedures to be performed on a subject matter.

(1) The option to perform an agreed upon procedures engagement is intended for a non-profit or for-profit Grant Recipient that is not subject to Generally Accepted Government Audit Standards (also known as the Yellow Book) published by the U.S. Government Accountability Office.

(2) The agreed upon procedures engagement will be conducted in accordance with attestation standards established by the American Institute of Certified Public Accountants.

(3) The certified public accountant is to perform procedures prescribed by the Institute and to report his or her findings attesting to whether the Grant Recipient records is in agreement with stated criteria.

(4) The agreed upon procedures apply to all current year expenditures for Grant Awards received by the Grant Recipient. Nothing herein prohibits the use of a statistical sample consistent with the American Institute of Certified Public Accountants' guidance regard-

ing government auditing standards and 2 CFR Part 200, Subpart F, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."

(5) At a minimum, the agreed upon procedures report should address:

(A) Processes and controls;

(B) The Grant Contract;

(C) Indirect Costs;

(D) Matching Funds, if appropriate;

(E) Grant Award expenditures (payroll and non-payroll related transactions);

(F) Equipment;

(G) Revenue Sharing and Program Income;

(H) Reporting; and

(I) Grant Award closeout.

(6) The certified public accountant should consider the specific Grant Mechanism and update or modify the procedures accordingly to meet the requirements of each Grant Award and the Grant Contract reviewed.

(f) If a deadline set by this rule falls on a Saturday, Sunday, or federal holiday as designated by the U.S. Office of Personnel Management, the required filing may be submitted on the next business day. The Institute will not consider a required filing delinquent if the Grant Recipient complies with this subsection.

§703.21. Monitoring Grant Award Performance and Expenditures.

(a) The Institute, under the direction of the Chief Compliance Officer, shall monitor Grant Awards to ensure that Grant Recipients comply with applicable financial, administrative, and programmatic terms and conditions and exercise proper stewardship over Grant Award funds. Such terms and conditions include requirements set forth in statute, administrative rules, and the Grant Contract.

(b) Methods used by the Institute to monitor a Grant Recipient's performance and expenditures may include:

(1) Financial Status Reports Review--The Institute shall review Grant Award expenditures reported by Grant Recipients on the quarterly Financial Status Reports and supporting documents to determine whether expenses charged to the Grant Award are:

(A) Allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds; and

(B) Adequately supported with documentation such as cost reports, receipts, third party invoices for expenses, or payroll information.

(2) Timely submission of Grant Award Reports--The Institute shall monitor the submission of all required reports and implement a process to ensure that Grant Award funds are not disbursed to a Grant Recipient with one or more delinquent reports.

(3) Grant Progress Reports--The Institute shall review Grant Progress Reports to determine whether sufficient progress is made consistent with the scope of work and timeline set forth in the Grant Contract.

(A) The Grant Progress Reports shall be submitted at least annually, but may be required more frequently pursuant to Grant Contract terms or upon request and reasonable notice of the Institute.

(B) Unless specifically stated otherwise herein, the annual Grant Progress Report shall be submitted within sixty (60) days after the anniversary of the effective date of the Grant Contract. The annual Grant Progress Report shall include at least the following information:

(i) An affirmative verification by the Grant Recipient of compliance with the terms and conditions of the Grant Contract;

(ii) A description of the Grant Recipient's progress made toward completing the scope of work specified by the Grant Contract, including information, data, and program metrics regarding the achievement of project goals and timelines;

(iii) The number of new jobs created and the number of jobs maintained for the preceding twelve month period as a result of Grant Award funds awarded to the Grant Recipient for the project;

(iv) An inventory of the equipment purchased for the project in the preceding twelve month period using Grant Award funds;

(v) A verification of the Grant Recipient's efforts to purchase from suppliers in this state more than 50 percent goods and services purchased for the project with grant funds;

(vi) A Historically Underutilized Businesses report;

(vii) Scholarly articles, presentations, and educational materials produced for the public addressing the project funded by the Institute;

(viii) The number of patents applied for or issued addressing discoveries resulting from the research project funded by the Institute;

(ix) A statement of the identities of the funding sources, including amounts and dates for all funding sources supporting the project;

(x) A verification of the amounts of Matching Funds dedicated to the research that is the subject of the Grant Award for the period covered by the annual report, which shall be submitted pursuant to the timeline in §703.11 of this title (relating to Requirement to Demonstrate Available Funds for Cancer Research Grants). In order to receive disbursement of grant funds, the most recently due verification of the amount of Matching Funds must be approved by CPRIT;

(xi) All financial information necessary to support the calculation of the Institute's share of revenues, if any, received by the Grant Recipient resulting from the project; and

(xii) A single audit determination form, which shall be submitted pursuant to the timeline in §703.13 of this title (relating to Audits and Investigations).

(C) Notwithstanding subparagraph (B) of this paragraph, in the event that the Grant Recipient and Institute execute the Grant Contract after the effective date of the Grant Contract, the Chief Program Officer may approve additional time for the Grant Recipient to prepare and submit the outstanding reports. The approval shall be in writing and maintained in the Institute's electronic Grants Management System. The Chief Program Officer's approval may cover more than one report and more than one fiscal quarter.

(D) In addition to annual Grant Progress Reports, a final Grant Progress Report shall be filed no more than ninety (90) days after the termination date of the Grant Contract. The final Grant Progress Report shall include a comprehensive description of the Grant Recipient's progress made toward completing the scope of work specified by the Grant Contract, as well as other information specified by the Institute.

(E) The Grant Progress Report will be evaluated pursuant to criteria established by the Institute. The evaluation shall be conducted under the direction of the Chief Prevention Officer, the Chief Product Development Officer, or the Chief Scientific Officer, as may be appropriate. Required financial reports associated with the Grant Progress Report will be reviewed by the Institute's financial staff. In order to receive disbursement of grant funds, the final progress report must be approved by CPRIT.

(F) If the Grant Progress Report evaluation indicates that the Grant Recipient has not demonstrated progress in accordance with the Grant Contract, then the Chief Program Officer shall notify the Chief Executive Officer and the General Counsel for further action.

(i) The Chief Program Officer shall submit written recommendations to the Chief Executive Officer and General Counsel for actions to be taken, if any, to address the issue.

(ii) The recommended action may include termination of the Grant Award pursuant to the process described in §703.14 of this chapter (relating to Termination, Extension, and Close Out of Grant Contracts, and De-Obligation of Grant Award Funds).

(G) If the Grant Recipient fails to submit required financial reports associated with the Grant Progress Report, then the Institute financial staff shall notify the Chief Executive Officer and the General Counsel for further action.

(H) In order to receive disbursement of grant funds, the most recently due progress report must be approved by CPRIT.

(I) If a Grant Recipient fails to submit the Grant Progress Report within 60 days of the anniversary of the effective date of the Grant Contract, then the Institute shall not disburse any Grant Award funds as reimbursement or advancement of Grant Award funds until such time that the delinquent Grant Progress Report is approved.

(J) In addition to annual Grant Progress Reports, Product Development Grant Recipients shall submit a Grant Progress Report at the completion of specific tranches of funding specified in the Award Contract. For the purpose of this subsection, a Grant Progress Report submitted at the completion of a tranche of funding shall be known as "Tranche Grant Progress Report."

(i) The Institute may specify other required reports, if any, that are required to be submitted at the time of the Tranche Grant Progress Report.

(ii) Grant Funds for the next tranche of funding specified in the Grant Contract shall not be disbursed until the Tranche Grant Progress Report has been reviewed and approved pursuant to the process described in this section.

(K) A Grant Award in the prevention program with a Grant Contract effective date within the last quarter of a state fiscal year (June 1-August 31) will have an initial reporting period beginning September 1 of the following state fiscal year.

(4) Desk Reviews--The Institute may conduct a desk review for a Grant Award to review and compare individual source documentation and materials to summary data provided during the Financial Status Report review for compliance with financial requirements set forth in the statute, administrative rules, and the Grant Contract.

(5) Site Visits and Inspection Reviews--The Institute may conduct a scheduled site visit to a Grant Recipient's place of business to review Grant Contract compliance and Grant Award performance issues. Such site visits may be comprehensive or limited in scope.

(6) Audit Reports--The Institute shall review audit reports submitted pursuant to §703.13 of this chapter (relating to Audits and Investigations).

(A) If the audit report findings indicate action to be taken related to the Grant Award funds expended by the Grant Recipient or for the Grant Recipient's fiscal processes that may impact Grant Award expenditures, the Institute and the Grant Recipient shall develop a written plan and timeline to address identified deficiencies, including any necessary Grant Contract amendments.

(B) The written plan shall be retained by the Institute as part of the Grant Contract record.

(c) All required Grant Recipient reports and submissions described in this section shall be made via an electronic grant portal designated by the Institute, unless specifically directed to the contrary in writing by the Institute.

(d) The Institute shall document the actions taken to monitor Grant Award performance and expenditures, including the review, approvals, and necessary remedial steps, if any.

(1) To the extent that the methods described in subsection (b) of this section are applied to a sample of the Grant Recipients or Grant Awards, then the Institute shall document the Grant Contracts reviewed and the selection criteria for the sample reviewed.

(2) Records will be maintained in the electronic Grant Management System as described in §703.4 of this chapter (relating to Grants Management System).

(e) The Chief Compliance Officer shall be engaged in the Institute's Grant Award monitoring activities and shall notify the General Counsel and Oversight Committee if a Grant Recipient fails to meaningfully comply with the Grant Contract reporting requirements and deadlines, including Matching Funds requirements.

(f) The Chief Executive Officer shall report to the Oversight Committee at least annually on the progress and continued merit of each Grant Program funded by the Institute. The written report shall also be included in the Annual Public Report. The report should be presented to the Oversight Committee at the first meeting following the publication of the Annual Public Report.

(g) The Institute may rely upon third parties to conduct Grant Award monitoring services independently or in conjunction with Institute staff.

(h) If a deadline set by this rule falls on a Saturday, Sunday, or federal holiday as designated by the U.S. Office of Personnel Management, the required filing may be submitted on the next business day. The Institute will not consider a required filing delinquent if the Grant Recipient complies with this subsection.

§703.22. Required Training for Grant Recipients.

(a) The Institute, under the direction of the Chief Compliance Officer, shall create a compliance training program for Grant Recipients addressing applicable financial, administrative, and programmatic requirements related to proper stewardship over Grant Award funds, including grant reporting.

(b) Initial Grant Recipient training program - A Grant Recipient that is approved for a Grant Award for the first time on or after September 1, 2015, shall complete an initial compliance training program. For purposes of this subsection, a Grant Recipient that has received at least one Grant Award prior to September 1, 2015, is not required to complete the initial compliance training program.

(1) The Chief Compliance Officer shall design the initial compliance training program.

(2) The Grant Recipient must complete the initial compliance training program prior to receiving disbursement of Grant Award funds, unless the Chief Compliance Officer finds good cause to disburse grant funds in advance of completing the initial compliance training program.

(3) Nothing herein prohibits the Chief Compliance Officer from requiring a Grant Recipient to complete the initial compliance training program.

(c) Annual Grant Recipient training program - All Grant Recipients shall complete an annual compliance training program by November 1, 2016, and then by December 31 [~~November 1~~] of each year thereafter that the Grant Recipient has at least one active Grant Award.

(1) The Chief Compliance Officer shall design the annual compliance training program.

(2) The Institute shall withhold disbursement of Grant Award funds if the Grant Recipient fails to complete the annual compliance training program by November 1, unless the Chief Compliance Officer finds good cause to disburse grant funds in advance of completing the annual compliance training program.

(d) Grant Recipient personnel required to attend training - The Grant Recipient's Authorized Signing Official and at least one other individual employed by the Grant Recipient must attend the trainings required by this rule.

(1) Upon a finding of good cause, the Chief Compliance Officer may allow the Grant Recipient to substitute another employee to attend a required training in place of the Authorized Signing Official.

(2) In the event that the Authorized Signing Official designated by the Grant Recipient changes on or after November 1, 2016, and the new Authorized Signing Official has not completed the annual compliance training program, the new Authorized Signing Official shall complete the annual compliance training program within 60 days of change. Failure to do so may result in the withholding of Grant Award funds until the training is completed.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 18, 2018.

TRD-201805461
Heidi McConnell
Chief Operating Officer
Cancer Prevention and Research Institute of Texas
Earliest possible date of adoption: February 3, 2019
For further information, please call: (512) 305-8487

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TITLE 28. INSURANCE

PART 1. TEXAS DEPARTMENT OF INSURANCE

CHAPTER 5. PROPERTY AND CASUALTY INSURANCE

SUBCHAPTER E. TEXAS WINDSTORM INSURANCE ASSOCIATION

DIVISION 1. PLAN OF OPERATION

28 TAC §5.4021

The Texas Department of Insurance proposes new 28 TAC §5.4021, relating to nonresident agent requirements under the Texas Windstorm Insurance Association (TWIA) plan of operation. The new section is necessary to implement House Bill 3018, 85th Legislature, Regular Session (2017).

EXPLANATION. HB 3018 added Insurance Code §2210.152(a)(2)(G), mandating that TWIA's plan of operation include "a requirement that a nonresident agent... may not offer or sell a Texas windstorm and hail insurance policy under (Chapter 2210) unless the nonresident agent's state of residence authorizes a resident agent licensed in (Texas) to act in the nonresident agent's state as an agent for that state's residual insurer of last resort for windstorm and hail insurance."

New §5.4021 amends the plan of operation to conform to the statute and requires that TWIA implement a process to prevent ineligible nonresident agents from offering or selling TWIA policies.

FISCAL NOTE AND LOCAL EMPLOYMENT IMPACT STATEMENT. Marianne Baker, director, Property and Casualty Lines Office, has determined that for each year of the first five years the proposed new section is in effect, there will be no measurable fiscal impact to state and local governments as a result of enforcement or administration of this proposal. This determination was made because the proposed new section does not add to or decrease state revenues or expenditures and because local governments are not involved in enforcing or complying with the proposed amendments.

Ms. Baker does not anticipate any measurable effect on local employment or the local economy as a result of this proposal.

PUBLIC BENEFIT AND COST NOTE. For each year of the first five years the proposed new section is in effect, Ms. Baker expects that administering the proposed section will have the public benefit of ensuring that TDI's rules conform to the Insurance Code and that Texas agents are treated fairly.

Ms. Baker expects that the proposed new section will not increase the cost of compliance with §2210.152 because it does not impose requirements beyond those in the statute. As a result, any cost associated with the rule is a result of the statutory change and not enforcement or administration of the proposed new section.

ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS. TDI has determined that the proposed new section will not have an adverse economic effect or a disproportionate economic impact on small or microbusinesses or on rural communities, because it only implements a statutorily required provision addressing the sale of Texas windstorm and hail insurance policies by Texas agents and nonresident agents. Therefore, in accordance with Government Code §2006.002(c), TDI has determined that a regulatory flexibility analysis is not required.

EXAMINATION OF COSTS UNDER GOVERNMENT CODE SECTION 2001.0045. TDI has determined that this proposal does not impose a cost beyond that required to implement HB 3018. In addition, no additional rule amendments or repeals

are required under Government Code §2001.0045 because proposed new §5.4021 is necessary to implement HB 3018.

GOVERNMENT GROWTH IMPACT STATEMENT. TDI has determined that for each year of the first five years that the proposed new rule is in effect, the rule or its implementation:

- will not create or eliminate a government program;

- will not require creating new employee positions or eliminating existing employee positions;

- will not require an increase or decrease in future legislative appropriations to the agency;

- will not require an increase or decrease in fees paid to the agency;

- will create a new regulation mandated by the Legislature at 28 TAC §5.4021;

- will not expand or repeal an existing regulation;

- will not increase or decrease the number of individuals subject to the rule's applicability; and

- will not positively or adversely affect the Texas economy.

TAKINGS IMPACT ASSESSMENT. TDI has determined that no private real property interests are affected by this proposal and that the proposal does not restrict or limit an owner's right to property that would otherwise exist in the absence of government action. As a result, this proposal does not constitute a taking or require a takings impact assessment under Government Code §2007.043.

REQUEST FOR PUBLIC COMMENT. TDI will consider any written comments on the proposal received by the department no later than 5:00 p.m., central time, on February 4, 2019. Send your comments to ChiefClerk@tdi.texas.gov, or to the Office of the Chief Clerk, Mail Code 113-2A, Texas Department of Insurance, P.O. Box 149104, Austin, Texas 78714-9104. To request a public hearing on the proposal, submit a request before the end of the comment period to ChiefClerk@tdi.texas.gov; or to the Office of the Chief Clerk, Mail Code 113-2A, Texas Department of Insurance, P.O. Box 149104, Austin, Texas 78714-9104. The request for public hearing must be separate from any comments and received by TDI no later than 5:00 p.m., central time, on February 4, 2019. If TDI holds a public hearing, TDI will consider written and oral comments presented at the hearing.

STATUTORY AUTHORITY. TDI proposes new 28 TAC §5.4021 under Insurance Code §§36.001, 2210.008(b), and 2210.151.

Section 36.001 provides that the Commissioner may adopt any rules necessary and appropriate to implement TDI powers and duties under the Insurance Code and other laws of the state.

Section 2210.008(b) authorizes the Commissioner to adopt rules as reasonable and necessary to implement Chapter 2210.

Section 2210.151 authorizes the Commissioner to adopt TWIA's plan of operation.

CROSS-REFERENCE TO STATUTE. Section 5.4021 implements Insurance Code §2210.152.

§5.4021. Agent Requirements.

A nonresident agent may not offer or sell a TWIA policy if the agent's state of residence does not authorize Texas residents to be agents for that state's windstorm and hail insurer of last resort. TWIA must implement a process to prevent unauthorized nonresident agents from offering or selling TWIA policies.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 19, 2018.

TRD-201805534
Norma Garcia
General Counsel
Texas Department of Insurance
Earliest possible date of adoption: February 3, 2019
For further information, please call: (512) 676-6584

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TITLE 31. NATURAL RESOURCES AND CONSERVATION

PART 1. GENERAL LAND OFFICE

CHAPTER 19. OIL SPILL PREVENTION AND RESPONSE

SUBCHAPTER F. DERELICT VESSELS AND STRUCTURES

31 TAC §19.70, §19.73

The General Land Office (GLO) proposes amendments to Title 31, Part 1, Chapter 19, Subchapter F, §19.70 and §19.73, relating to the procedures for enforcement of §40.108 and §40.254 of the Oil Spill Prevention and Response Act (OSPRA) of 1981, Chapter 40 of the Texas Natural Resources Code. These amendments are proposed for consistency with statutory revisions in H.B 1625 (Acts 2017, 85th Legislature, Chapter 259, effective September 1, 2017).

BACKGROUND AND ANALYSIS OF PROPOSED RULES

Sections 40.108(c) and 40.254 of OSPRA contain procedures for ordering the removal and disposal of derelict vessels or structures left in a wrecked, derelict, or substantially dismantled condition, and for the removal and disposal of such vessels and structures. Under certain conditions, the Commissioner may order the removal of a vessel or structure without notice or an opportunity for hearing. Prior to the statutory amendment, the Commissioner could order removal without notice or an opportunity for a hearing only in instances where the vessel or structure was involved in an actual or threatened unauthorized discharge of oil.

As amended, §40.108(c) and §40.254 of OSPRA add two additional procedures the Commissioner may use to order the removal of derelict vessels or structures abandoned in coastal waters without providing notice and an opportunity for a hearing. The proposed rule amendments reflect these statutory changes. The new procedures in the statute allow the Commissioner to order the removal of derelict vessels or structures in cases where (1) there is an imminent and significant threat to life or property, or (2) where there is a significant navigation hazard, as part of a response action without notice or a hearing. In instances where the Commissioner removes a vessel without a hearing, the vessel will be removed to a safe storage facility. The Commissioner will provide notice to the vessel owner in accordance with §40.254 of OSPRA before disposal of a vessel. The pro-

posed rule amendments are necessary to reflect the statutory changes.

19.70 Applicability and Purpose

The proposed amendment for this section will indicate that it is implementing H.B. 1625 (Acts 2017, 85th Legislature, Chapter 259, effective September 1, 2017).

19.73 Procedures for Removal or Disposal by an Authority of Authorized Public Entity

The proposed amendment for this section reflects the statutory changes in §40.108(c) and §40.254 of OSPRA that provide additional procedures by which the Commissioner may order the removal of a derelict vessel or structure without notice or an opportunity for a hearing. Before the statutory amendments, the Commissioner could order the removal of a derelict vessel or structure without notice or an opportunity for hearing only when the vessel or structure was involved in an actual or threatened unauthorized discharge of oil. The amendments provide new procedures so that the Commissioner also may obtain an order to remove a derelict vessel or structure in cases where there is an imminent and significant threat to life or property or where there is a significant navigation hazard, as part of a response action without notice or a hearing.

FISCAL AND EMPLOYMENT IMPACTS

Mr. Greg Pollock, Senior Deputy Commissioner for the GLO's Coastal Protection Division, has determined that for each year of the first five years the amended sections as proposed are in effect there will be no fiscal implications for state government as a result of enforcing or administering the amended sections because the GLO does not anticipate that the proposed amendments will result in additional removals and costs. Rather, the proposed amendments will make the removal process more efficient. There will be no fiscal impact on local governments for each of the first five years the amended sections as proposed are in effect as a result of enforcing or administering the rules since the removal process is funded by the GLO.

Mr. Pollock has determined that the proposed rule amendments will not increase the costs of compliance for small businesses, micro-businesses, or large businesses or individuals required to comply with the amended rules. There will be no impact on rural communities. Current law prohibits a person from abandoning a vessel or structure in or on coastal waters in a derelict condition without the consent of the Commissioner. The proposed amended rules simply establish additional procedures for removal and disposal of abandoned vessels or structures without notice or a hearing.

The GLO has determined that a local employment impact statement on these proposed rule amendments is not required because the proposed amendments will not adversely affect any local economy in a material manner for the first five years they will be in effect. The GLO has also determined that an economic impact statement and regulatory flexibility analysis on these proposed rule amendments is not required, because the proposed amendments do not create new requirements and will not have a material adverse economic effect on small businesses.

PUBLIC BENEFIT

Mr. Pollock has determined that the public will benefit from the proposed rule amendments because they provide more efficient procedures for removal of derelict vessels and structures. The proposed amended rules allow the Commissioner to more quickly respond to those derelict vessels and structures that pose the most severe threat to public health, safety, and welfare, as well as the environment, since they streamline the process for removal without notice or a hearing.

GOVERNMENT GROWTH IMPACT STATEMENT

The GLO prepared a Government Growth Impact Statement assessment for this proposed rulemaking. The proposed rulemaking does not create or eliminate a government program, will not require an increase or decrease in future legislative appropriations to the agency, will not require the creation of new employee positions nor eliminate current employee positions, nor will it require an increase or decrease in fees paid to the agency. The proposed rule amendments do not create, limit, or repeal existing regulations, but rather reflect statutory amendments and provide additional procedures streamlining the process for issuing orders to remove derelict or abandoned vessels or structures that pose a threat to the environment or that are safety hazards without notice or an opportunity for a hearing. The proposed rules do not increase or decrease the number of individuals subject to the rule's applicability.

During the first five years that the proposed rules would be in effect, it is not anticipated that there will be an adverse impact on the state's economy. The proposed amendments are expected to improve environmental protection and safety.

CONSISTENCY WITH CMP

The proposed amended rules concerning procedures for removal of derelict vessels and structures implement §40.108 and §40.254 of OSPRA as amended by H.B 1625 and are not subject to the Coastal Management Program (CMP), 31 TAC §505.11(c), relating to the Actions and Rules subject to the CMP. Therefore, consistency review is not required.

TAKINGS IMPACT ASSESSMENT

The GLO has evaluated the rule amendments to determine whether Texas Government Code, Chapter 2007 (Private Real Property Rights Preservation Act), is applicable and a detailed takings assessment is required. The GLO has determined that the proposed amendments do not affect private real property in a manner that requires real property owners to be compensated as provided by the Fifth and Fourteenth Amendments to the United States Constitution or Article I, Sections 17 and 19 of the Texas Constitution. Therefore, a detailed takings assessment is not required.

ENVIRONMENTAL REGULATORY ANALYSIS

The GLO has evaluated the proposed rule amendments in light of the regulatory analysis requirements of Texas Government Code §2001.0225 and determined that the action is not subject to §2001.0225 because it does not exceed express requirements of state law and does not meet the definition of a "major environmental rule" as defined in the statute. "Major environmental rule" means a rule of which the specific intent is to protect the environment or reduce risks to human health from environmental exposure and that may adversely affect the economy, a sector of the economy, productivity, competition, jobs, the environment, or public health and safety of the state or a sector of the state. The proposed amended rules are not anticipated to adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, or the public health and safety of the state or a sector of the state because the proposed amended rules simply implement statutory changes in Texas Natural Resources Code §40.108 and §40.254. These

sections, as amended by H.B. 1625, provide the Commissioner with additional procedures for ordering the removal of derelict vessels and structures without notice or a hearing and therefore make the removal actions more expedient under certain circumstances.

PUBLIC COMMENT REQUEST

To comment on the proposed rulemaking, please send a written comment to Mr. Walter Talley, Texas Register Liaison, Texas General Land Office, P.O. Box 12873, Austin, Texas 78711, facsimile number (512) 463-6311 or email to walter.talley@glo.texas.gov. Written comments must be received no later than 5:00 p.m., thirty (30) days from the date of publication of this proposal in the *Texas Register.*

STATUTORY AUTHORITY

The amended sections are proposed under OSPRA, Texas Natural Resources Code, §40.007(a), which gives the Commissioner of the GLO the authority to promulgate rules necessary and convenient to the administration of OSPRA, and §40.108(e), which authorizes the Commissioner of the GLO to adopt regulations relating to a system for prioritizing the removal or disposal of derelict vessels or structures.

The proposed amendments affect §19.70 and §19.73 of this title.

§19.70. Applicability and Purpose.

(a) (No change.)

(b) Purpose. There has been an increase in the number of derelict and abandoned vessels that are either grounded or anchored upon publicly or privately owned submerged lands. These vessels are public nuisances and safety hazards as they often pose hazards to navigation, detract from the aesthetics of Texas coastal waterways, and threaten the environment with the potential release of oil and hazardous substances. The costs associated with the disposal of derelict and abandoned vessels are substantial, and in many cases there is no way to track down the current vessel owners in order to seek compensation. As a result, the costs associated with the removal of derelict vessels becomes a burden on public entities and the taxpaying public. This subchapter is adopted to implement H.B 2096 (Acts 2005, 79th Legislature, Chapter 216, effective September 1, 2005), ~~and~~ H.B. 3306 (Acts 2009, 81st Legislature, Chapter 1324, effective September 1, 2009), and H.B. 1625 (Acts 2017, 85th Legislature, Chapter 259, effective September 1, 2017).

§19.73. Procedure for Removal or Disposal by an Authorized Public Entity.

(a) Before removing or disposing of a derelict vessel or structure, an authorized public entity must obtain an order from the commissioner for removal or disposal after notice and an opportunity for hearing as provided in §40.254, Texas Natural Resources Code, except that the commissioner may remove a vessel or structure involved in an actual or threatened unauthorized discharge of oil, a vessel or structure that creates an imminent and significant threat to life or property, or a vessel or structure that creates a significant navigation hazard as part of a response action without a hearing.

(b) - (d) (No change.)

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 17, 2018.

TRD-201805446
Mark A. Havens
Chief Clerk and Deputy Land Commissioner
General Land Office
Earliest possible date of adoption: February 3, 2019
For further information, please call: (512) 475-1859

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PART 10. TEXAS WATER DEVELOPMENT BOARD

CHAPTER 371. DRINKING WATER STATE REVOLVING FUND

The Texas Water Development Board ("TWDB" or "board") proposes amendments to 31 Texas Administrative Code (TAC) §371.2, relating to projects and activities eligible for assistance; §371.14, relating to lending rates; §371.70, relating to financial assistance secured by bonds or other authorized securities; §371.71, relating to financial assistance secured by promissory notes and deeds of trust; and §371.85 relating to final accounting.

BACKGROUND AND SUMMARY OF THE FACTUAL BASIS FOR THE PROPOSED AMENDMENTS.

The TWDB proposes to amend various provisions in 31 TAC Chapter 371 to provide clarity on the TWDB's procedures to those seeking and receiving financial assistance from the board. The specific provisions being amended and the reasons for the amendments are addressed in more detail below.

SECTION BY SECTION DISCUSSION OF PROPOSED AMENDMENTS.

31 TAC §371.2. Projects and Activities Eligible for Assistance.

Section 371.2 is amended to correct the heading of the subsection concerning what applicants are ineligible for assistance.

31 TAC §371.14. Lending Rates.

Section 371.14 is amended to streamline the procedure for setting fixed interest rates for loans with the TWDB's procedure for setting interest rates for entities adopting bond ordinances or resolutions. Currently, the procedure for loans states that interest rates may not be set earlier than five business days before both the TWDB and the borrower execute the loan agreement. The amendment will change the procedure for loans to clarify that interest rates may be set no earlier than five business days before the borrower's execution of the loan agreement.

31 TAC §371.70. Financial Assistance Secured by Bonds or Other Authorized Securities.

Section 371.70 is amended to remove the requirement that the partial redemption of bonds or other authorized securities be made in inverse order of maturity.

31 TAC §371.71. Financial Assistance Secured by Promissory Notes and Deeds of Trust.

Section 371.71 is amended to clarify that before closing financial assistance secured by promissory notes and deeds of trust that applicants must establish a dedicated source of revenue for repayment of the financial assistance. This is already a closing requirement for loans and bonds, but the procedure was not in the TWDB rules. This is required by 42 U.S.C.A §300j-12(f)(1)(C).

31 TAC §371.85. Final Accounting.

Section 371.85 is amended to streamline the final accounting provision with the TWDB's other financial assistance programs. Currently, 31 TAC §363.42 provides that after final accounting any surplus loan funds may be used in a manner as approved by the executive administrator. Section 371.85 is amended to match this procedure.

FISCAL NOTE: COSTS TO STATE AND LOCAL GOVERNMENTS

Ms. Rebecca Trevino, Chief Financial Officer, has determined that there will be no significant fiscal implications for state or local governments as a result of the proposed rulemaking. For the first five years these rules are in effect, there is no expected additional cost to state or local governments resulting from their administration.

These rules are not expected to result in reductions in costs to either state or local governments. There is no change in costs for state and local governments because the proposed amendments are only clarifications to the language in the rules. These rules are not expected to have any impact on state or local revenues. The rules do not require any increase in expenditures for state or local governments as a result of administering these rules. Additionally, there are no foreseeable implications relating to state or local governments' costs or revenue resulting from these rules.

Because these rules will not impose a cost on regulated persons, the requirement included in Texas Government Code §2001.0045 to repeal a rule does not apply. Furthermore, the requirement in §2001.0045 does not apply because these rules are necessary to receive a source of federal funds and are necessary to comply with federal law.

The board invites public comment regarding this fiscal note. Written comments on the fiscal note may be submitted to the contact person at the address listed under the Submission of Comments section of this preamble.

PUBLIC BENEFITS AND COSTS

Ms. Rebecca Trevino also has determined that for each year of the first five years the proposed rulemaking is in effect, the public will benefit from the rulemaking as it is intended to provide greater clarity to those seeking and receiving financial assistance from the board.

LOCAL EMPLOYMENT IMPACT STATEMENT

The board has determined that a local employment impact statement is not required because the proposed rules do not adversely affect a local economy in a material way for the first five years that the proposed rules are in effect because it will impose no new requirements on local economies. The board also has determined that there will be no adverse economic effect on small businesses, micro-businesses, or rural communities as a result of enforcing this rulemaking. The board also has determined that there is no anticipated economic cost to persons who are required to comply with the rulemaking as proposed. Therefore, no regulatory flexibility analysis is necessary.

DRAFT REGULATORY IMPACT ANALYSIS DETERMINATION

The board reviewed the proposed rulemaking in light of the regulatory analysis requirements of Texas Government Code §2001.0225, and determined that the rulemaking is not subject to Texas Government Code, §2001.0225, because it does not meet the definition of a "major environmental rule" as defined in the Administrative Procedure Act. A "major environmental rule" is defined as a rule with the specific intent to protect the environment or reduce risks to human health from environmental exposure, a rule that may adversely affect in a material way the economy or a sector of the economy, productivity, competition, jobs, the environment, or the public health and safety of the state or a sector of the state. The intent of the rulemaking is to streamline the procedures for those seeking and receiving financial assistance from the board.

Even if the proposed rules were a major environmental rule, Texas Government Code, §2001.0225 still would not apply to this rulemaking because Texas Government Code, §2001.0225 only applies to a major environmental rule, the result of which is to: (1) exceed a standard set by federal law, unless the rule is specifically required by state law; (2) exceed an express requirement of state law, unless the rule is specifically required by federal law; (3) exceed a requirement of a delegation agreement or contract between the state and an agency or representative of the federal government to implement a state and federal program; or (4) adopt a rule solely under the general powers of the agency instead of under a specific state law. This rulemaking does not meet any of these four applicability criteria because it: (1) does not exceed any federal law; (2) does not exceed an express requirement of state law; (3) does not exceed a requirement of a delegation agreement or contract between the state and an agency or representative of the federal government to implement a state and federal program; and (4) is not proposed solely under the general powers of the agency, but rather is proposed under the authority of Texas Water Code §§15.604, 15.605, and 16.093. Therefore, the proposed amendments do not fall under any of the applicability criteria in Texas Government Code, §2001.0225.

The board invites public comment regarding this draft regulatory impact analysis determination. Written comments on the draft regulatory impact analysis determination may be submitted to the contact person at the address listed under the Submission of Comments section of this preamble.

TAKINGS IMPACT ASSESSMENT

The board evaluated the proposed rules and performed an analysis of whether it constitutes a taking under Texas Government Code, Chapter 2007. The specific purpose of the rules is to provide clarity to those seeking and receiving financial assistance from the board. The proposed rules would substantially advance this stated purpose by updating internal references regarding TWDB financial assistance programs and streamlining the procedures across the financial assistance programs.

The board's analysis indicates that Texas Government Code, Chapter 2007 does not apply to the proposed rules because this is an action that is reasonably taken to fulfill an obligation mandated by state and federal law, which is exempt under Texas Government Code, §2007.003(b)(4). The board is the agency that provides financial assistance for the construction of water, wastewater, flood control, and other related projects.

Nevertheless, the board further evaluated the proposed rules and performed an assessment of whether it constitutes a taking under Texas Government Code, Chapter 2007. Promulgation and enforcement of the proposed rules would be neither a statutory nor a constitutional taking of private real property. Specifically, the proposed regulation does not affect a landowner's rights in private real property because this rule-

making does not burden nor restrict or limit the owner's right to property and reduce its value by 25% or more beyond that which would otherwise exist in the absence of the regulation. In other words, these rules require compliance with state and federal laws regarding financial assistance under the state revolving funds without burdening or restricting or limiting an owner's right to property and reducing its value by 25% or more. Therefore, the proposed rules do not constitute a taking under Texas Government Code, Chapter 2007.

GOVERNMENT GROWTH IMPACT STATEMENT

The board reviewed the proposed rulemaking in light of the government growth impact statement requirements of Texas Government §2001.0221 and has determined for the first five years the proposed rule would be in effect, the proposed rules will not: (1) create or eliminate a government program; (2) require the creation of new employee positions or the elimination of existing employee positions; (3) require an increase or decrease in future legislative appropriations to the agency; (4) require an increase or decrease in fees paid to the agency; (5) create a new regulation; (6) expand, limit, or repeal an existing regulation; (7) increase or decrease the number of individuals subject to the rule's applicability; or (8) positively or adversely affect this state's economy. The proposed rules provide greater clarity on the financial assistance process.

SUBMISSION OF COMMENTS

Written comments on the proposed rulemaking may be submitted by mail to Mr. Todd Chenoweth, Office of General Counsel, Texas Water Development Board, P.O. Box 13231, Austin, Texas 78711-3231, by email to rulescomments@twdb.texas.gov, or by fax to (512) 475-2053. Comments will be accepted until 5:00 p.m. of the 31st day following publication in the *Texas Register*.

SUBCHAPTER A. GENERAL PROGRAM REQUIREMENTS

31 TAC §371.2

STATUTORY AUTHORITY

This rulemaking is proposed under the authority of Texas Water Code §6.101, which provides the TWDB with the authority to adopt rules necessary to carry out the powers and duties in the Water Code and other laws of the State, and also under the authority of Texas Water Code §§15.604, 15.605, and 16.093.

Chapters 15 and 16 of the Texas Water Code are affected by this rulemaking.

§371.2. Projects and Activities Eligible for Assistance.

(a) - (c) (No change.)

(d) Ineligible applicants [~~projects~~]. Assistance from the Fund may not be provided to:

(1) Federally-owned public water systems or for-profit noncommunity water systems.

(2) Systems that lack the technical, financial, and managerial capability to ensure compliance with the requirements of the Act, unless the assistance will ensure compliance and the owners or operators of the systems agree to undertake feasible and appropriate changes in operations to ensure compliance over the long term.

(3) Systems that are in significant noncompliance with any national primary drinking water regulation or variance, unless:

(A) The purpose of the assistance is to address the cause of the significant noncompliance and will ensure that the systems return to compliance; or

(B) The purpose of the assistance is unrelated to the cause of the significant noncompliance and the systems are on enforcement schedules (for maximum contaminant level and treatment technique violations) or have compliance plans (for monitoring and reporting violations) to return to compliance.

(e) - (f) (No change.)

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 18, 2018.

TRD-201805466
Todd Chenoweth
General Counsel
Texas Water Development Board
Earliest possible date of adoption: February 3, 2019
For further information, please call: (512) 463-7686

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SUBCHAPTER B. FINANCIAL ASSISTANCE

31 TAC §371.14

STATUTORY AUTHORITY

This rulemaking is proposed under the authority of Texas Water Code §6.101, which provides the TWDB with the authority to adopt rules necessary to carry out the powers and duties in the Water Code and other laws of the State, and also under the authority of Texas Water Code §§15.604, 15.605, and 16.093.

Chapters 15 and 16 of the Texas Water Code are affected by this rulemaking.

§371.14. Lending Rates.

(a) (No change.)

(b) Procedure for setting fixed interest rates.

(1) The executive administrator will set fixed interest rates as described in the IUP and further determined in this section, on a date that is:

(A) no earlier than five business days prior to the adoption of the political subdivision's bond ordinance or resolution or the borrower's execution of a loan agreement; and

(B) not more than 45 days before the anticipated closing of a commitment from the Board.

(2) After 45 days from the assignment of the interest rate, rates may be extended only with the executive administrator's approval.

(c) - (f) (No change.)

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Todd Chenoweth
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Texas Water Development Board
Earliest possible date of adoption: February 3, 2019
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SUBCHAPTER G. LOAN CLOSINGS AND AVAILABILITY OF FUNDS

31 TAC §371.70, §371.71

STATUTORY AUTHORITY

This rulemaking is proposed under the authority of Texas Water Code §6.101, which provides the TWDB with the authority to adopt rules necessary to carry out the powers and duties in the Water Code and other laws of the State, and also under the authority of Texas Water Code §§15.604, 15.605, and 16.093.

Chapters 15 and 16 of the Texas Water Code are affected by this rulemaking.

§371.70. Financial Assistance Secured by Bonds or Other Authorized Securities.

(a) Applicability and required documents. This section applies to closings for financial assistance with entities issuing bonds or other authorized securities. The following documents are required for closing financial assistance secured by bonds or other authorized securities:

(1) evidence that applicable requirements and regulations of all identified local, state, and federal agencies having jurisdiction have been met, including but not limited to permits and authorizations;

(2) a certified copy of the ordinance or resolution adopted by the governing body authorizing the issuance of debt to be sold to the Board that is acceptable to the executive administrator. The ordinance or resolution shall have sections providing as follows:

(A) - (H) (No change.)

~~[(I) that the partial redemption of bonds or other authorized securities be made in inverse order of maturity;]~~

(I) ~~[(J)]~~ that insurance coverage be obtained and maintained in an amount sufficient to protect the Board's interest in the project;

(J) ~~[(K)]~~ that the Applicant, or an obligated person for whom financial or operating data is presented, will undertake, either individually or in combination with other issuers of the Applicant's obligations or obligated persons, in a written agreement or contract to comply with requirements for continuing disclosure on an ongoing basis as required by Securities and Exchange Commission (SEC) rule 15c2-12 and determined as if the Board were a Participating Underwriter within the meaning of such rule, such continuing disclosure undertaking being for the benefit of the Board and the beneficial owner of the political subdivision's obligations, if the Board sells or otherwise transfers such obligations, and the beneficial owners of the Board's bonds if the political subdivision is an obligated person with respect to such bonds under rule 15c2-12. The ordinance or resolution shall also contain any other requirements of the SEC or the IRS relating to arbitrage, private activity bonds, or other relevant requirements regarding the securities held by the Board;

(K) ~~[(L)]~~ the maintenance of current, accurate, and complete records and accounts in accordance with generally accepted accounting principles to demonstrate compliance with requirements in the financial assistance documents;

(L) ~~[(M)]~~ that the Applicant shall annually submit an audit, prepared by a certified public accountant in accordance with generally accepted auditing standards;

(M) ~~[(N)]~~ that the Applicant shall submit a final accounting within 60 days of the completion of the project;

(N) ~~[(O)]~~ that the Applicant shall document the adoption and implementation of an approved water conservation program for the duration of the financial assistance;

(O) ~~[(P)]~~ the Applicant's agreement to comply with special environmental conditions specified in the Board's environmental finding as well as with any applicable Board laws or rules relating to use of the financial assistance;

(P) ~~[(Q)]~~ that the Applicant shall establish a dedicated source of revenue for repayment of the financial assistance;

(Q) ~~[(R)]~~ that interest payments shall commence no later than one year after the date of closing;

(R) ~~[(S)]~~ that annual principal payments will commence no later than one year after completion of project construction; and

(S) ~~[(T)]~~ any other recitals mandated by the executive administrator;

(3) - (11) (No change.)

(b) - (d) (No change.)

§371.71. Financial Assistance Secured by Promissory Notes and Deeds of Trust.

(a) - (b) (No change.)

(c) Documents required for closing. The executive administrator shall ensure that the following documents have been submitted prior to closing financial assistance secured by promissory notes and deeds of trust:

(1) evidence that applicable requirements and regulations of all identified local, state, and federal agencies having jurisdiction have been met, including but not limited to permits and authorizations;

(2) an executed promissory note and loan agreement in a form approved by the executive administrator;

(3) a Deed of Trust and Security Agreement that shall contain a first mortgage lien evidenced by a deed of trust on all the real and personal property of the water system; provided, however, these are not needed if the financial assistance consists of 100 percent principal forgiveness;

(4) an owner's title insurance policy for the benefit of the Board covering all the real property identified in the deed of trust; provided, however, these are not needed if the financial assistance consists of 100 percent principal forgiveness;

(5) evidence that the rates on which the Applicant intends to rely for repayment of the financial assistance have received final and binding approval from the Utility Commission and, for Applicants required to utilize a surcharge account, evidence that the approval of the Utility Commission was conditioned on the creation of a surcharge account;

(6) a certified copy of the resolution adopted by the governing body authorizing the indebtedness and a certificate from the secretary of the governing body attesting to adoption of the resolution in accordance with the by-laws or rules of the governing body and in compliance with the Open Meetings Act, if applicable;

(7) a legal opinion from Applicant's counsel that provides:

(A) that the entity has the legal authority to enter into the loan agreement and to execute a promissory note;

(B) that the entity is not in breach or default of any state or federal order, judgment, decree, or other instrument which would have a material effect on the loan transaction;

(C) that there is no pending suit, action, proceeding, or investigation by a public entity that would materially adversely affect the enforceability or validity of the required financial assistance documents;

(D) evidence that the entity is in good standing with the Texas Office of the Secretary of State; and

(E) a statement relating to any other issues deemed relevant by the executive administrator.

(8) evidence that an approved water conservation plan has been adopted and will be implemented through the life of the project;

(9) evidence of the Applicant's agreement to comply with special environmental conditions contained in the Board's environmental finding;

(10) evidence that the Applicant shall establish a dedicated source of revenue for repayment of the financial assistance;

(11) [~~(10)~~] evidence that the Applicant has adopted final water rates and charges that are not subject to appeal to the Utility Commission;

(12) [~~(11)~~] copies of executed service and revenue contracts;

(13) [~~(12)~~] evidence that the Applicant has the technical, managerial, and financial capacity to maintain the system unless the use of the funds will be to ensure that the system has the technical, managerial, and financial capacity to comply with the national primary or applicable state drinking water regulations over the long term;

(14) [~~(13)~~] if the project will result in the development of surface or groundwater resources, the Applicant shall demonstrate that it has the right to use the quantity of water necessary for project effectiveness and efficiency. Upon receipt of the information, the executive administrator shall prepare a finding that the Applicant has a reasonable expectation of obtaining the water rights necessary for project implementation prior to any release of funds for planning, land acquisition, and design activities. A written water rights certification must be prepared by the executive administrator before funds can be released for construction activities based upon a showing by the Applicant that the necessary water rights have been acquired;

(15) [~~(14)~~] when any portion of the financial assistance is to be held in an escrow account, the Applicant shall execute an escrow agreement, approved as to form and substance by the executive administrator; and

(16) [~~(15)~~] any other documents relevant to the particular transaction.

(d) - (f) (No change.)

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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TRD-201805469

Todd Chenoweth
General Counsel
Texas Water Development Board
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For further information, please call: (512) 463-7686

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SUBCHAPTER H. CONSTRUCTION AND POST-CONSTRUCTION REQUIREMENTS

31 TAC §371.85

STATUTORY AUTHORITY

This rulemaking is proposed under the authority of Texas Water Code §6.101, which provides the TWDB with the authority to adopt rules necessary to carry out the powers and duties in the Water Code and other laws of the State, and also under the authority of Texas Water Code §§15.604, 15.605, and 16.093.

Chapters 15 and 16 of the Texas Water Code are affected by this rulemaking.

§371.85. Final Accounting.

(a) (No change.)

(b) After the final accounting, the executive administrator shall notify the Applicant if remaining surplus funds exist and advise the Applicant that the remaining surplus funds may be used in a manner as approved by the executive administrator.[~~, as specified in any applicable bond ordinance, for:~~]

[~~(1) payment of bonds in inverse order of maturity;~~]

[~~(2) deposit into the interest and sinking fund; or~~]

[~~(3) deposit to a reserve fund.~~]

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Todd Chenoweth
General Counsel
Texas Water Development Board
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CHAPTER 375. CLEAN WATER STATE REVOLVING FUND

The Texas Water Development Board ("TWDB" or "board") proposes amendments to 31 Texas Administrative Code (TAC) §375.15, relating to lending rates; 31 TAC §375.18, relating to principal forgiveness; 31 TAC §375.91, relating to financial assistance secured by bonds or other authorized securities; 31 TAC §375.92, relating to financial assistance secured by promissory notes and deeds of trust; and 31 TAC §375.106, relating to final accounting.

BACKGROUND AND SUMMARY OF THE FACTUAL BASIS FOR THE PROPOSED AMENDMENT.

The TWDB proposes to amend various provisions in 31 TAC Chapter 375 to provide clarity on the TWDB's procedures to those seeking and receiving financial assistance from the board. The specific provisions being amended and the reasons for the amendments are addressed in more detail below.

SECTION BY SECTION DISCUSSION OF PROPOSED AMENDMENTS.

31 TAC §375.15. Lending Rates.

Section 375.15 is amended to streamline the procedure for setting fixed interest rates for loans with the TWDB's procedure for setting interest rates for entities adopting bond ordinances or resolutions. Currently, the procedure for loans states that interest rates may not be set earlier than five business days before both the TWDB and the borrower execute the loan agreement. The amendment will change the procedure for loans to clarify that interest rates may be set no earlier than five business days before the borrower's execution of the loan agreement.

31 TAC §375.18. Principal Forgiveness.

Section 375.18 is amended to clarify that the board may provide principal forgiveness for financial assistance in accordance with the federal appropriations acts and for eligible activities as detailed in the TWDB's Intended Use Plan.

31 TAC §375.91. Financial Assistance Secured by Bonds or Other Authorized Securities.

Section 375.91 is amended to remove the requirement that the partial redemption of bonds or other authorized securities be made in inverse order of maturity.

31 TAC §375.92. Financial Assistance Secured by Promissory Notes and Deeds of Trust.

Section 375.92 is amended to clarify that before closing financial assistance secured by promissory notes and deeds of trust, applicants must establish a dedicated source of revenue for repayment of the financial assistance. This is already a closing requirement for loans and bonds, but the procedure was not in the TWDB rules. This is required by 33 U.S.C.A §1383(d)(1)(C).

31 TAC §375.106. Final Accounting.

Section 375.106 is amended to streamline the final accounting provision with the TWDB's other financial assistance programs. Currently, 31 TAC §363.42 provides that after final accounting, any surplus loan funds may be used in a manner as approved by the executive administrator. Section 375.106 is amended to match this procedure.

FISCAL NOTE: COSTS TO STATE AND LOCAL GOVERNMENTS

Ms. Rebecca Trevino, Chief Financial Officer, has determined that there will be no significant fiscal implications for state or local governments as a result of the proposed rulemaking. For the first five years these rules are in effect, there is no expected additional cost to state or local governments resulting from their administration.

These rules are not expected to result in reductions in costs to either state or local governments. There is no change in costs for state and local governments because the proposed amendments are only clarifications to the language in the rules. These rules are not expected to have any impact on state or local revenues. The rules do not require any increase in expenditures for state or local governments as a result of administering these rules. Additionally, there are no foreseeable implications relating to state or local governments' costs or revenue resulting from these rules.

Because these rules will not impose a cost on regulated persons, the requirement included in Texas Government Code Section 2001.0045 to repeal a rule does not apply. Furthermore, the requirement in Section 2001.0045 does not apply because these rules are necessary to receive a source of federal funds and are necessary to comply with federal law.

The board invites public comment regarding this fiscal note. Written comments on the fiscal note may be submitted to the contact person at the address listed under the Submission of Comments section of this preamble.

PUBLIC BENEFITS AND COSTS

Ms. Rebecca Trevino also has determined that for each year of the first five years the proposed rulemaking is in effect, the public will benefit from the rulemaking as it is intended to provide greater clarity to those seeking and receiving financial assistance from the board.

LOCAL EMPLOYMENT IMPACT STATEMENT

The board has determined that a local employment impact statement is not required because the proposed rules do not adversely affect a local economy in a material way for the first five years that the proposed rules are in effect because it will impose no new requirements on local economies. The board also has determined that there will be no adverse economic effect on small businesses, micro-businesses, or rural communities as a result of enforcing this rulemaking. The board also has determined that there is no anticipated economic cost to persons who are required to comply with the rulemaking as proposed. Therefore, no regulatory flexibility analysis is necessary.

DRAFT REGULATORY IMPACT ANALYSIS DETERMINATION

The board reviewed the proposed rulemaking in light of the regulatory analysis requirements of Texas Government Code §2001.0225 and determined that the rulemaking is not subject to Texas Government Code §2001.0225 because it does not meet the definition of a "major environmental rule" as defined in the Administrative Procedure Act. A "major environmental rule" is defined as a rule with the specific intent to protect the environment or reduce risks to human health from environmental exposure, a rule that may adversely affect in a material way the economy or a sector of the economy, productivity, competition, jobs, the environment, or the public health and safety of the state or a sector of the state. The intent of the rulemaking is to streamline the procedures for those seeking and receiving financial assistance from the board.

Even if the proposed rules were a major environmental rule, Texas Government Code, §2001.0225 still would not apply to this rulemaking because Texas Government Code, §2001.0225 only applies to a major environmental rule, the result of which is to: (1) exceed a standard set by federal law, unless the rule is specifically required by state law; (2) exceed an express requirement of state law, unless the rule is specifically required by federal law; (3) exceed a requirement of a delegation agreement or contract between the state and an agency or representative of the federal government to implement a state and federal program; or (4) adopt a rule solely under the general powers of the agency instead of under a specific state law. This rulemaking does not meet any of these four applicability criteria because it: (1) does not exceed any federal law; (2) does not exceed

an express requirement of state law; (3) does not exceed a requirement of a delegation agreement or contract between the state and an agency or representative of the federal government to implement a state and federal program; and (4) is not proposed solely under the general powers of the agency, but rather is proposed under the authority of Texas Water Code §§15.604, 15.605, and 16.093. Therefore, the proposed amendments do not fall under any of the applicability criteria in Texas Government Code, §2001.0225.

The board invites public comment regarding this draft regulatory impact analysis determination. Written comments on the draft regulatory impact analysis determination may be submitted to the contact person at the address listed under the Submission of Comments section of this preamble.

TAKINGS IMPACT ASSESSMENT

The board evaluated the proposed rules and performed an analysis of whether it constitutes a taking under Texas Government Code, Chapter 2007. The specific purpose of the rules is to provide clarity to those seeking and receiving financial assistance from the board. The proposed rules would substantially advance this stated purpose by updating internal references regarding TWDB financial assistance programs and streamlining the procedures across the financial assistance programs.

The board's analysis indicates that Texas Government Code, Chapter 2007 does not apply to the proposed rules because this is an action that is reasonably taken to fulfill an obligation mandated by state and federal law, which is exempt under Texas Government Code, §2007.003(b)(4). The board is the agency that provides financial assistance for the construction of water, wastewater, flood control, and other related projects.

Nevertheless, the board further evaluated the proposed rules and performed an assessment of whether it constitutes a taking under Texas Government Code, Chapter 2007. Promulgation and enforcement of the proposed rules would be neither a statutory nor a constitutional taking of private real property. Specifically, the proposed regulation does not affect a landowner's rights in private real property because this rulemaking does not burden nor restrict or limit the owner's right to property and reduce its value by 25% or more beyond that which would otherwise exist in the absence of the regulation. In other words, these rules require compliance with state and federal laws regarding financial assistance under the state revolving funds without burdening or restricting or limiting an owner's right to property and reducing its value by 25% or more. Therefore, the proposed rules do not constitute a taking under Texas Government Code, Chapter 2007.

GOVERNMENT GROWTH IMPACT STATEMENT

The board reviewed the proposed rulemaking in light of the government growth impact statement requirements of Texas Government §2001.0221 and has determined for the first five years the proposed rule would be in effect, the proposed rule will not: (1) create or eliminate a government program; (2) require the creation of new employee positions or the elimination of existing employee positions; (3) require an increase or decrease in future legislative appropriations to the agency; (4) require an increase or decrease in fees paid to the agency; (5) create a new regulation; (6) expand, limit, or repeal an existing regulation; (7) increase or decrease the number of individuals subject to the rule's applicability; or (8) positively or adversely affect this state's economy. The proposed rules provide greater clarity on the financial assistance process.

SUBMISSION OF COMMENTS

Written comments on the proposed rulemaking may be submitted by mail to Mr. Todd Chenoweth, Office of General Counsel, Texas Water Development Board, P.O. Box 13231, Austin, Texas 78711-3231, by email to rulescomments@twdb.texas.gov, or by fax to (512) 475-2053. Comments will be accepted until 5:00 p.m. of the 31st day following publication in the *Texas Register*.

SUBCHAPTER B. FINANCIAL ASSISTANCE

31 TAC §375.15, §375.18

STATUTORY AUTHORITY

This rulemaking is proposed under the authority of Texas Water Code §6.101, which provides the TWDB with the authority to adopt rules necessary to carry out the powers and duties in the Water Code and other laws of the State, and also under the authority of Texas Water Code §§15.604, 15.605, and 16.093.

Chapters 15 and 16 of the Texas Water Code are affected by this rulemaking.

§375.15. Lending Rates.

(a) (No change.)

(b) Procedure for setting fixed interest rates.

(1) The executive administrator will set fixed interest rates as described in the IUP and further determined in this section, on a date that is:

(A) no earlier than five business days prior to the adoption of the political subdivision's bond ordinance or resolution or the borrower's execution of a loan agreement; and

(B) not more than 45 days before the anticipated closing of a commitment from the Board.

(2) After 45 days from the assignment of the interest rate, rates may be extended only with the executive administrator's approval.

(c) - (e) (No change.)

§375.18. Principal Forgiveness.

(a) The Board may provide principal forgiveness for financial assistance in accordance with 33 U.S.C. §1383(i) or federal appropriations acts:

(1) for an entity that meets the affordability criteria established in this chapter and in the IUP for a Disadvantaged Community; [or]

(2) to implement a process, material, technique, or technology:

(A) to address water-efficiency goals;

(B) to address energy-efficiency goals;

(C) to mitigate stormwater runoff; and/or

(D) to encourage sustainable project planning, design, and construction; or [.]

(3) for any other eligible activity as detailed in the Intended Use Plan.

(b) (No change.)

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 18, 2018.

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Todd Chenoweth
General Counsel
Texas Water Development Board
Earliest possible date of adoption: February 3, 2019
For further information, please call: (512) 463-7686

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SUBCHAPTER G. LOAN CLOSINGS AND AVAILABILITY OF FUNDS

31 TAC §375.91, §375.92

STATUTORY AUTHORITY

This rulemaking is proposed under the authority of Texas Water Code §6.101, which provides the TWDB with the authority to adopt rules necessary to carry out the powers and duties in the Water Code and other laws of the State, and also under the authority of Texas Water Code §§15.604, 15.605, and 16.093.

Chapters 15 and 16 of the Texas Water Code are affected by this rulemaking.

§375.91. Financial Assistance Secured by Bonds or Other Authorized Securities.

(a) Applicability and required documents. This section applies to closings for financial assistance with entities issuing bonds or other authorized securities. The following documents are required for closing financial assistance secured by bonds or other authorized securities:

(1) evidence that applicable requirements and regulations of all identified local, state, and federal agencies having jurisdiction have been met, including but not limited to permits and authorizations;

(2) a certified copy of the ordinance or resolution adopted by the governing body authorizing the issuance of debt to be sold to the Board that is acceptable to the executive administrator. The ordinance or resolution shall have sections providing as follows:

(A) - (H) (No change.)

~~[(I) that the partial redemption of bonds or other authorized securities be made in inverse order of maturity;]~~

(I) [~~(J)~~] that insurance coverage be obtained and maintained in an amount sufficient to protect the Board's interest in the project;

(J) [~~(K)~~] that the Applicant, or an obligated person for whom financial or operating data is presented, will undertake, either individually or in combination with other issuers of the Applicant's obligations or obligated persons, in a written agreement or contract to comply with requirements for continuing disclosure on an ongoing basis as required by Securities and Exchange Commission (SEC) rule 15c2-12 and determined as if the Board were a Participating Underwriter within the meaning of such rule, such continuing disclosure undertaking being for the benefit of the Board and the beneficial owner of the political subdivision's obligations, if the Board sells or otherwise transfers such obligations, and the beneficial owners of the Board's bonds if the political subdivision is an obligated person with respect to such bonds under rule 15c2-12. The ordinance or resolution shall also contain any other requirements of the SEC or the IRS relating arbitrage, private activity bonds or other relevant requirements regarding the securities held by the Board;

(K) [~~(L)~~] the maintenance of current, accurate, and complete records and accounts in accordance with generally accepted accounting principles to demonstrate compliance with requirements in the financial assistance documents;

(L) [~~(M)~~] that the Applicant shall annually submit an audit, prepared by a certified public accountant in accordance with generally accepted auditing standards;

(M) [~~(N)~~] that the Applicant shall submit a final accounting within 60 days of the completion of the project;

(N) [~~(O)~~] that the Applicant shall document the adoption and implementation of an approved water conservation program for the duration of the financial assistance;

(O) [~~(P)~~] the Applicant's agreement to comply with special environmental conditions specified in the Board's environmental finding as well as with any applicable Board laws or rules relating to use of the financial assistance;

(P) [~~(Q)~~] that the Applicant shall establish a dedicated source of revenue for repayment of the financial assistance;

(Q) [~~(R)~~] that interest payments shall commence no later than one year after the date of closing;

(R) [~~(S)~~] that annual principal payments will commence no later than one year after completion of project construction; and

(S) [~~(T)~~] any other recitals mandated by the executive administrator;

(3) - (9) (No change.)

(b) - (c) (No change.)

§375.92. Financial Assistance Secured by Promissory Notes and Deeds of Trust.

(a) - (b) (No change.)

(c) Documents required for closing. The executive administrator shall ensure that the following documents have been submitted prior to closing financial assistance secured by promissory notes and deeds of trust:

(1) evidence that applicable requirements and regulations of all identified local, state, and federal agencies having jurisdiction have been met, including but not limited to permits and authorizations;

(2) an executed promissory note and loan agreement in a form approved by the executive administrator;

(3) a Deed of Trust and Security Agreement that shall contain a first mortgage lien evidenced by a deed of trust on all the real and personal property of the water system;

(4) an owner's title insurance policy for the benefit of the Board covering all the real property identified in the deed of trust;

(5) evidence that the rates on which the Applicant intends to rely for repayment of the financial assistance have received final and binding approval from the Utility Commission and, for Applicants required to utilize a surcharge account, evidence that the approval of the Utility Commission was conditioned on the creation of a surcharge account;

(6) a certified copy of the resolution adopted by the governing body authorizing the indebtedness and a certificate from the secretary of the governing body attesting to adoption of the resolution in accordance with the by-laws or rules of the governing body and in compliance with the Open Meetings Act, if applicable;

(7) a legal opinion from Applicant's counsel that provides:

(A) that the entity has the legal authority to enter into the loan agreement and to execute a promissory note;

(B) that the entity is not in breach or default of any state or federal order, judgment, decree, or other instrument which would have a material effect on the loan transaction;

(C) that there is no pending suit, action, proceeding, or investigation by a public entity that would materially adversely affect the enforceability or validity of the required financial assistance documents;

(D) evidence that the entity is in good standing with the Texas Office of the Secretary of State; and

(E) a statement relating to any other issues deemed relevant by the executive administrator.

(8) evidence that an approved water conservation plan has been adopted and will be implemented through the life of the project;

(9) evidence of the Applicant's agreement to comply with special environmental conditions contained in the Board's environmental finding;

(10) evidence that the Applicant shall establish a dedicated source of revenue for repayment of the financial assistance;

(11) [~~10~~] evidence that the Applicant has adopted final water rates and charges that are not subject to appeal to the Utility Commission;

(12) [~~11~~] copies of executed service and revenue contracts;

(13) [~~12~~] when any portion of the financial assistance is to be held in an escrow account, the Applicant shall execute an escrow agreement, approved as to form and substance by the executive administrator; and

(14) [~~13~~] any other documents relevant to the particular transaction.

(d) - (f) (No change.)

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on December 18, 2018.

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Todd Chenoweth
General Counsel
Texas Water Development Board
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For further information, please call: (512) 463-7686

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SUBCHAPTER H. CONSTRUCTION AND POST CONSTRUCTION REQUIREMENTS

31 TAC §375.106

STATUTORY AUTHORITY

This rulemaking is proposed under the authority of Texas Water Code §6.101, which provides the TWDB with the authority to adopt rules necessary to carry out the powers and duties in the Water Code and other laws of the State, and also under the authority of Texas Water Code §§15.604, 15.605, and 16.093. Chapters 15 and 16 of the Texas Water Code are affected by this rulemaking.

§375.106. Final Accounting.

(a) (No change.)

(b) After the final accounting, the executive administrator shall notify the Applicant if remaining surplus funds exist and advise the Applicant that the remaining surplus funds may be used in a manner as approved by the executive administrator. [~~, as specified in any applicable bond ordinance, for:~~

[~~(1) payment of bonds in inverse order of maturity;~~]

[~~(2) deposit into the interest and sinking fund; or~~]

[~~(3) deposit to a reserve fund.~~]

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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TITLE 37. PUBLIC SAFETY AND CORRECTIONS

PART 15. TEXAS FORENSIC SCIENCE COMMISSION

CHAPTER 651. DNA, CODIS, FORENSIC ANALYSIS, AND CRIME LABORATORIES SUBCHAPTER C. FORENSIC ANALYST LICENSING PROGRAM

37 TAC §651.217

The Texas Forensic Science Commission ("Commission") proposes an amendment to 37 TAC §651.217 to correct a citation in the rule. The amendment is a non-substantial edit to correct a mistake in citation where §651.217(c)(2) cites §651.217(d)-(g) and should cite §651.216(d)-(g). The amendments are made in accordance with the Commission's forensic analyst licensing authority under Tex. Code. Crim. Proc. art. 38.01 §4-a.

Fiscal Note. Leigh M. Savage, Associate General Counsel of the Texas Forensic Science Commission, has determined that for each year of the first five years the proposed amendment will be in effect, there will be no fiscal impact to state or local governments as a result of the enforcement or administration of the proposal. The amendment makes a non-substantial edit to a cite reference in the rule and does not change any current requirements for forensic analysts.

Rural Impact Statement. The Commission expects no adverse economic effect on rural communities as the proposed amendment does not impose any direct costs or fees on municipalities

in rural communities. The amendment makes a non-substantial edit to a cite reference in the rule and does not change any current requirements for forensic analysts.

Public Benefit/Cost Note. Leigh M. Savage, Associate General Counsel of the Texas Forensic Science Commission, has also determined that for each year of the first five years the proposed amendment is in effect, the anticipated public benefit will be notification to forensic analysts of the State's licensing rules with regard to performing forensic analysis.

Economic Impact Statement and Regulatory Flexibility Analysis for Small and Micro Businesses. As required by the Government Code §2006.002(c) and (f), Leigh M. Savage, Associate General Counsel of the Texas Forensic Science Commission, has determined that the proposed amendment will not have an adverse economic effect on any small or micro business because the amendment makes a non-substantial edit to a cite reference in the rule and does not change any current requirements for forensic analysts.

Takings Impact Assessment. Leigh M. Savage, Associate General Counsel of the Texas Forensic Science Commission, has determined that no private real property interests are affected by this proposal and that this proposal does not restrict or limit an owner's right to property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking or require a takings impact assessment under the Government Code §2007.043.

Government Growth Impact Statement. Leigh M. Savage, Associate General Counsel of the Texas Forensic Science Commission, has determined that there is no anticipated government growth impact as the proposal does not change any current requirements for forensic analysts.

Requirement for Rule Increasing Costs to Regulated Persons. Leigh M. Savage, Associate General Counsel of the Texas Forensic Science Commission, has determined that there is no anticipated increased costs to regulated persons as the proposal does not change any current requirements for forensic analysts.

Request for Public Comment. The Texas Forensic Science Commission invites comments on the proposal from any member of the public. Please submit comments to Leigh M. Savage, 1700 North Congress Avenue, Suite 445, Austin, Texas 78701 or leigh@fsc.texas.gov. Comments must be received by February 4, 2019, to be considered by the Commission.

Statutory Authority. The amendment is proposed under Tex. Code Crim. Proc. art 38.01 §4-a.

Cross reference to statute. The proposal affects 37 TAC §651.217.

§651.217. Ineligibility for License Based on Criminal Conviction.

(a) A proceeding before the Commission to establish factors required to be considered under this section is governed by Chapter 2001, Government Code.

(b) Guidelines for consideration of criminal convictions. If an applicant has a criminal conviction above a Class C misdemeanor, the applicant may not be qualified to hold a forensic analyst license.

(1) Convictions that may trigger a denial. The Commission may suspend or revoke a forensic analyst license, disqualify a person from receiving a license, refuse to renew a person's license or deny to a person the opportunity to take the general forensic licensing examination on the grounds the person has been convicted of:

(A) an offense that directly relates to the duties and responsibilities associated with an analyst's license;

(B) an offense that does not directly relate to the duties and responsibilities associated with an analyst's license and that was committed less than five years before the date the person applies for a license;

(C) an offense listed in Article 42A.054, Code of Criminal Procedure; or

(D) a sexually violent offense as defined by Article 62.001, Code of Criminal Procedure.

(2) A forensic analyst license holder's license may be revoked on the license holder's imprisonment following a felony conviction, felony community supervision, revocation of parole, or revocation of mandatory supervision.

(3) An offense from another state containing elements substantially similar to the enumerated offenses under the Texas Penal Code shall be considered under this section the same way as the offense would have been considered had it been committed in Texas.

(4) Offenses that apply to category paragraph (1)(A) of this subsection because they directly relate to the duties and responsibilities associated with an analyst's license may include, but are not limited to:

(A) Misrepresentation (e.g., fraud, extortion, bribery, theft by check, and deceptive business practices);

(B) Failure to register as a sex offender (as required by the Texas Code of Criminal Procedure, Chapter 62);

(C) Property Crimes, such as theft or burglary;

(D) Crimes against persons, such as homicide, kidnapping, and assault;

(E) Drug crimes, such as possession;

(F) Multiple DWI and DUI crimes;

(G) All felony convictions; and

(H) Misdemeanors above a Class C misdemeanor and felony convictions considered by Texas courts to be crimes of moral turpitude.

(5) Consequences. In the event of a criminal conviction, the Commission may take one of the following courses of action:

(A) Declare a prospective applicant unsuitable for a license;

(B) Deny a renewal application for an existing license;

(C) Revoke or suspend an existing license; or

(D) Deny a person the opportunity to take the general forensic analyst licensing examination.

(6) Determining whether there are grounds to deny. There are four general factors the Commission considers in determining whether a particular criminal conviction should be grounds to deny, revoke or suspend a license:

(A) the nature and seriousness of the crime;

(B) the relationship of the crime to the purposes for requiring a license to engage in the analyst's occupation;

(C) the extent to which a license might offer an opportunity to engage in further criminal activity of the same type as that in which the person previously had been involved; and

(D) the relationship of the crime to the ability, capacity, or fitness required to perform the duties and discharges the responsibilities of the analyst's work.

(7) Determining an applicant's fitness to perform the duties. In determining an applicant's fitness to perform the duties and discharge the responsibilities of a forensic analyst who has been convicted of a crime, the Commission considers, in addition to the factors listed in paragraph (5) of this subsection:

(A) the extent and nature of the person's past criminal activity;

(B) the age of the person when the crime was committed;

(C) the amount of time that has elapsed since the person's last criminal activity;

(D) the conduct and work activity of the person before and after the criminal activity;

(E) evidence of the person's rehabilitation or rehabilitative effort while incarcerated or after release; and

(F) other evidence of the person's fitness, including letters or recommendations from:

(i) prosecutors and law enforcement and correctional officers who prosecuted, arrested, or had custodial responsibility to the person;

(ii) the sheriff or chief of police in the community where the person resides; and

(iii) any other person in contact with the convicted person.

(8) An applicant has the responsibility, to the extent possible, to obtain and provide to the Commission the recommendations of the prosecution, law enforcement, and correctional authorities as required by paragraph (7) (F)(i)-(iii) of this subsection.

(9) In addition to fulfilling the requirements of paragraph (8) of this subsection, the applicant shall furnish proof in the form required by the Commission that the applicant has:

(A) maintained a record of steady employment;

(B) supported the applicant's dependents;

(C) maintained a record of good conduct; and

(D) paid all outstanding court costs, supervision fees, fines, and restitution ordered in any criminal case in which the applicant has been convicted.

(c) Notice and Review of Suspension, Revocation or Denial of License. If the Commission suspends or revokes a license or denies a person a license or the opportunity to be examined for a license because of the person's prior conviction of a crime and the relationship of the crime to the license, the Commission shall notify the person in writing of:

(1) the reason for the suspension, revocation, denial, or disqualification;

(2) the review procedure provided by §651.216(d)-(g)[~~§651.217(d)-(g)~~] of this subchapter; and

(3) the earliest date the person may appeal the action of the Commission.

(d) Judicial Review. A person whose license has been suspended or revoked or who has been denied a license or the opportunity to take the general examination as set forth in this subchapter and who has exhausted the person's administrative appeals may file an action in district court in Travis County for review of the evidence presented to the Commission and the decision of the Commission.

(e) A petition for judicial review must be filed not later than the 30th day after the date the Commission's decision is final and appealable.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Leigh Savage
Associate General Counsel
Texas Forensic Science Commission
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For further information, please call: (512) 936-0661

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TITLE 40. SOCIAL SERVICES AND ASSISTANCE

PART 20. TEXAS WORKFORCE COMMISSION

CHAPTER 850. VOCATIONAL REHABILITATION SERVICES ADMINISTRATIVE RULES AND PROCEDURES

The Texas Workforce Commission (TWC) proposes amendments to the following sections of Chapter 850, relating to Vocational Rehabilitation Services Administrative Rules and Procedures:

Subchapter A. Vocational Rehabilitation General Rules, §§850.3 - 850.6, and §850.11

Subchapter C. Councils, Board, and Committees, §§850.32 - 850.35

Subchapter D. Privacy and Confidentiality, §850.50 and §850.51

Subchapter F. Memorandum of Understanding, §§850.130 - 850.132

TWC proposes the repeal of the following sections of Chapter 850, relating to Vocational Rehabilitation Services Administrative Rules and Procedures:

Subchapter A. Vocational Rehabilitation General Rules, §850.1, §850.2, and §§850.7 - 850.10

Subchapter B. Historically Underutilized Businesses, §§850.20 - 850.23

Subchapter C. Councils, Board, and Committees, §850.30, §850.31, and §§850.40 - 850.43

TWC proposes the repeal of the following subchapter of Chapter 850, relating to Vocational Rehabilitation Services Administrative Rules and Procedures, in its entirety:

Subchapter E. Vocational Rehabilitation Services Appeals and Hearing Procedures, §§850.60 - 850.84 and §§850.100 - 850.111

TWC proposes the following new subchapter of Chapter 850, relating to Vocational Rehabilitation Services Administrative Rules and Procedures:

Subchapter E. Vocational Rehabilitation Services Appeals and Hearing Procedures, §§850.60 - 850.89

PART I. PURPOSE, BACKGROUND, AND AUTHORITY

The purpose of the proposed Chapter 850 rule change is to align the chapter with TWC's operation of the Vocational Rehabilitation (VR) services program. Texas Labor Code §351.002 transferred the administration of VR services from the Texas Department of Assistive and Rehabilitative Services (DARS) to TWC, effective September 1, 2016.

To ensure continuity and avoid any impacts on customers, the administrative rules shared by all DARS programs were duplicated into Chapters 850, 857, and 858 of TWC's rules upon transfer of the programs. Because the rules established DARS' administrative framework and served all DARS programs, they overlap certain existing TWC administrative rules and contain numerous references to programs that were not transferred to TWC.

In order to streamline TWC rules and accurately reflect TWC's program administration, several amendments are necessary to integrate and align overlapping sections and update outdated terms and procedures to align with TWC's current program operation.

TWC is eliminating the division titles from the organizational structure of this chapter.

PART II. EXPLANATION OF INDIVIDUAL PROVISIONS

(Note: Minor editorial changes are made that do not change the meaning of the rules and, therefore, are not discussed in the Explanation of Individual Provisions.)

SUBCHAPTER A. VOCATIONAL REHABILITATION GENERAL RULES

TWC proposes the following amendments to Subchapter A:

§850.1. Purpose

Section 850.1 is repealed to align with current TWC rulemaking practices, in which purpose and legal authority are provided in a rule's preamble text.

§850.2. Legal Authority

Section 850.2 is repealed to align with current TWC rulemaking practices, in which purpose and legal authority are provided in a rule's preamble text.

§850.3. Definitions

Section 850.3 is amended to remove a reference to "DARS", replace with "Agency" and replace a reference to the two former DARS divisions with "Vocational Rehabilitation Division (VRD)."

§850.4. Opportunities for Citizen Participation

Section 850.4 is amended to replace "DARS" with "Agency" and "Commission," as appropriate, and "people" with "individuals."

§850.5. Complaints

Section 850.5 is amended to reflect TWC's operation of the program and to replace "DARS" with "Agency" and "Commission," as appropriate, "consumer" with "customer," and "person" with "individual." Subsections (d) and (e) of this section are repealed as they relate to services which did not transfer to TWC.

§850.6. Cooperation with Other Public Agencies

Section 850.6 is amended to replace "DARS" with "Agency" and "people" with "individuals."

§850.7. Criminal History Information on Applicants for Employment

Section 850.7 is repealed because it concerns internal procedures addressed within TWC's Human Resources procedures and therefore is unnecessary.

§850.8. Use of Criminal History Information in Contracting

Section 850.8 is repealed because it concerns VR contracting, which is addressed in Chapter 858 and is being updated and amended in a separate rulemaking, and therefore is unnecessary.

§850.9. Fees for Department Publications

Section 850.9 is repealed because it is inconsistent with TWC's practice of providing TWC publications for free and therefore is unnecessary.

§850.10. Gifts and Donations to TWC

Section 850.10 is repealed because it overlaps existing TWC rules and therefore is unnecessary.

§850.11. Qualified Vocational Rehabilitation Counselor (QVRC)

Section 850.11 is amended to replace references to the two former DARS divisions with "Vocational Rehabilitation Division (VRD)" and to reflect current TWC job titles.

SUBCHAPTER B. HISTORICALLY UNDERUTILIZED BUSINESSES

TWC proposes the following amendments to Subchapter B:

§850.20. Purpose

Section 850.20 is repealed because it overlaps existing TWC rules that are being updated and amended in a separate rulemaking and therefore is unnecessary.

§850.21. Legal Authority

Section 850.21 is repealed because it overlaps existing TWC rules that are being updated and amended in a separate rulemaking and therefore is unnecessary.

§850.22. Definitions

Section 850.22 is repealed because it overlaps existing TWC rules that are being updated and amended in a separate rulemaking and therefore is unnecessary.

§850.23. Adoption of Rules

Section 850.23 is repealed because it overlaps existing TWC rules that are being updated and amended in a separate rulemaking and therefore is unnecessary.

SUBCHAPTER C. COUNCILS, BOARD, AND COMMITTEES

TWC proposes the following amendments to Subchapter C:

§850.30. Purpose

Section 850.30 is repealed to align with current TWC rulemaking practices, in which purpose and legal authority are provided in a rule's preamble text.

§850.31. Legal Authority

Section 850.31 is repealed to align with current TWC rulemaking practices, in which purpose and legal authority are provided in a rule's preamble text.

§850.32. Definitions

Section 850.32 is amended to replace "DARS" with "Agency."

§850.33. Tasks

Section 850.33 is amended to replace references to the former DARS divisions with "Vocational Rehabilitation Division (VRD)" and to replace "consumer" with "customer" and "people" with "individuals."

§850.34. Reports

Section 850.34 is amended to replace (DARS) "commissioner" with "Commission."

§850.35. Funding

Section 850.35 is amended to replace "DARS" with "Agency."

DIVISION 2. BET ELECTED COMMITTEE OF MANAGERS (ECM)

§850.40. Purpose

Section 850.40 is repealed because it overlaps existing TWC rules that are being updated and amended in a separate rulemaking and therefore is unnecessary.

§850.41. Legal Authority

Section 850.41 is repealed because it overlaps existing TWC rules that are being updated and amended in a separate rulemaking and therefore is unnecessary.

§850.42. Definitions

Section 850.42 is repealed because it overlaps existing TWC rules that are being updated and amended in a separate rulemaking and therefore is unnecessary.

§850.43. Substantive Rules

Section 850.43 is repealed because it overlaps existing TWC rules that are being updated and amended in a separate rulemaking and therefore is unnecessary.

SUBCHAPTER D. PRIVACY AND CONFIDENTIALITY

TWC proposes the following amendments to Subchapter D:

§850.50. Privacy Policies

Section 850.50 is amended to replace "DARS" with "Agency" and "person" with "individual;" to update the address for submitting requests for correction of information; to remove a reference to social security disability determination cases which did not transfer to TWC; and to update procedures relating to verifying documentation for submitting requests for correction of information.

§850.51. Confidentiality of Consumer Information in Vocational Rehabilitation Services Program

Section 850.51 is amended to replace "DARS" with "Agency" and "consumer" with "customer."

SUBCHAPTER E. VOCATIONAL REHABILITATION SERVICES APPEALS AND HEARING PROCEDURES

TWC proposes new Subchapter E:

§850.60. Scope

New §850.60 retains the provisions of §850.101, concurrently proposed for repeal, renaming it with modifications to clarify the content and to update cross-references, terminology, and citations.

§850.61. Definitions

New §850.61(1), the definition of "Act," retains the provisions of §850.62(1), concurrently proposed for repeal.

New §850.61(2), the definition of "appellant," retains without modification the provisions of §850.62(2), concurrently proposed for repeal.

New §850.61(3), the definition of "applicant," retains the provisions of §850.62(3), concurrently proposed for repeal, with modifications to align with the federal definitions at 34 CFR Part 361.

New §850.61(4), the definition of "authorized representative," retains the provisions of §850.62(4), concurrently proposed for repeal, with modifications to replace "person" with "individual".

New §850.61(5), the definition of "counselor," retains the provisions of §850.3(2), concurrently proposed for repeal, with modifications to replace "DARS" with "Agency".

New §850.61(6), the definition of "customer," is added to mean an applicant or an individual who is receiving VR services.

New §850.61(7), the definition of "discovery," retains without modification the provisions of §850.62(8), concurrently proposed for repeal.

New §850.61(8), the definition of "eligible individual," retains the provisions of §850.62(9), concurrently proposed for repeal, with modifications to replace "DARS" with "Agency".

New §850.61(9), the definition of "hearing," retains the provisions of §850.62(10), concurrently proposed for repeal, with modifications to update chapter reference.

New §850.61(10), the definition of "impartial hearing officer," retains the provisions of §850.62(11), concurrently proposed for repeal.

New §850.61(11), the definition of "Individualized Plan for Employment," is added to mean a plan developed for each individual determined to be eligible for VR services, in accordance with 34 CFR Part 361.

New §850.61(12), the definition of "parent," retains the provisions of §850.62(12), concurrently proposed for repeal, with modifications to update terminology.

New §850.60(13), the definition of "party," retains the provisions of §850.62(13), concurrently proposed for repeal, with modifications to update terminology.

New §850.61(14), the definition of "record," retains the provisions of §850.62(15), concurrently proposed for repeal, with modifications to update terminology.

New §850.61(15), the definition of "State Plan," retains the provisions of §850.3(3), concurrently proposed for repeal, with modifications to update terminology.

§850.62. Filing a Request for Review

New §850.62, the process for filing a request for review, retains the provisions of §850.103, concurrently proposed for repeal, with modifications to replace "DARS" with "Agency" and to update the location for the hearings coordinator. Additionally, per 34 CFR §361.57(a), wording is clarified to indicate that a request for review may also be filed by an individual's authorized representative.

§850.63. Informal Dispute Resolution

New §850.63 is added to reflect TWC's development of an informal process for resolving a request for review without conducting mediation or a formal hearing, consistent with 34 CFR §361.57(c) and internal Agency practice.

§850.64. Time for Hearing

New §850.64 retains the provisions of §850.64, concurrently proposed for repeal, with modifications to replace "DARS" with "Agency" and to integrate references to the two previous VR divisions.

§850.65. Mediation Procedures

New §850.65 retains the provisions of §850.83, concurrently proposed for repeal, with modifications to replace "DARS" with "Agency," and wording is clarified to provide instructions for filing mediation requests and to indicate that a request for mediation may also be filed by an individual's authorized representative and that parties may present evidence and other information to support their position.

§850.66. Assignment of Impartial Hearing Officer

New §850.66 retains the provisions of §850.65, concurrently proposed for repeal, with modifications to replace "DARS" with "Agency" and to integrate references to the two previous VR divisions. Outdated references to programs no longer at TWC have been removed, and cross-references have been updated.

§850.67. Powers and Duties of Impartial Hearing Officer

New §850.67 retains the provisions of §850.66, concurrently proposed for repeal, with modifications to remove an outdated reference to the DARS commissioner and to update terminology.

§850.68. Substitution of Impartial Hearing Officer

New §850.68 retains the provisions of §850.67, concurrently proposed for repeal, with modifications to update terminology and to clarify options for withdrawal or reassignment.

§850.69. Reasonable Accommodations

New §850.69 retains the provisions of §850.68, concurrently proposed for repeal, with modifications to remove an outdated reference to programs no longer at TWC, replace "DARS" with "Agency," and to update terminology.

§850.70. Appearance of Parties at Hearings; Representation

New §850.70 retains the provisions of §850.69, concurrently proposed for repeal, with modifications to replace "DARS" with "Agency" and to update terminology.

§850.71. Failure to Attend Hearing and Default

New §850.71 retains the provisions of §850.70, concurrently proposed for repeal, with modifications to update terminology.

§850.72. Witness Fees

New §850.72 retains the provisions of §850.71, concurrently proposed for repeal, with modifications to replace "DARS" with "Agency" and to update terminology.

§850.73. Prehearing Conferences

New §850.73 retains the provisions of §850.72, currently proposed for repeal, with modifications to update terminology.

§850.74. Dismissal without Hearing

New §850.74 retains the provisions of §850.73, concurrently proposed for repeal, with modifications to update terminology.

§850.75. Conduct of Hearing

New §850.75 retains the provisions of §850.74, concurrently proposed for repeal, with modifications to update terminology.

§850.76. Order of Proceedings

New §850.76 retains the provisions of §850.75, concurrently proposed for repeal, with modifications to replace "DARS" with "Agency," integrate references to the two former DARS VR divisions, and update terminology. Subsection (c) is removed, as it contains outdated references to programs no longer at TWC. Subsections are re-lettered.

§850.77. Rules of Evidence

New §850.77 retains the provisions of §850.76, concurrently proposed for repeal, with modifications to replace "DARS" with "Agency" and to update terminology.

§850.78. Transcription of Proceedings

New §850.78 retains the provisions of §850.77, concurrently proposed for repeal, with modifications to replace "DARS" with "Agency" and to update terminology.

§850.79. Prepared Testimony

New §850.79 retains the provisions of §850.78, concurrently proposed for repeal, with modifications to update terminology.

§850.80. Pleadings

New §850.80 is amended to replace "DARS" with "Agency," incorporate §850.104(a), concurrently proposed for repeal, into subsection (d), replace subsection (g) with subsection (c) of §850.104, relating to Filings and concurrently proposed for repeal, and update terminology.

§850.81. Discovery and Mandatory Disclosures

New §850.81 retains the provisions of §850.105, relating to Discovery and Mandatory Disclosures, and concurrently proposed for repeal, replaces "DARS" with "Agency," and updates terminology. New wording clarifies that the copy to be provided to the appellant of the appellant's record of services is provided to the extent pertinent to the determination that is the subject of the request for review.

§850.82 Documentary Evidence and Official Notice

New §850.82 retains the provisions of §850.106, relating to Documentary Evidence and Official Notice, concurrently proposed for repeal. "DARS" is replaced with "Agency," references to the two previous VR divisions are consolidated, citations are updated to clarify the applicability of the chapter to proceedings related to the Independent Living Services for Older Individuals Who Are Blind program and the Business Enterprises of Texas program. Additionally, terminology is updated.

§850.83. Continuance

New §850.83 retains and re-letters the provisions of §850.80, relating to Continuance, and concurrently proposed for repeal, with modifications to update terminology.

§850.84. Impartial Hearing Officer Decision

New §850.84 retains the provisions of §850.107, relating to Impartial Hearing Officer Decision and concurrently proposed for repeal, replaces "DARS" with "Agency," updates locations and titles, integrates references to the two previous VR divisions, and updates citations and terminology.

§850.85. Finality of the Hearing Officer's Decision

New §850.85 retains the provisions of §850.108, relating to Finality of the Hearing Officer's Decision, and concurrently proposed for repeal, replacing "DARS" with "Agency" and updating terminology.

§850.86. Implementation of Final Decision

New §850.86 retains the provisions of §850.109, relating to Implementation of Final Decision and concurrently proposed for repeal, with modifications to update terminology.

§850.87. Motion for Reconsideration

New §850.87 retains and re-letters the provisions of §850.81, relating to Motion for Reconsideration, and concurrently proposed for repeal, removes a reference to a program that was not transferred to TWC, replaces "DARS" with "Agency," updates the location for filing the motion for reconsideration with the hearings coordinator, with modifications to update terminology. Additionally, new §850.86 incorporates §850.110, also relating to Motion for Reconsideration, concurrently proposed for repeal.

§850.88. Civil Action

New §850.88 retains and re-letters the provisions of §850.82, relating to Civil Action, and concurrently proposed for repeal, with modifications to update terminology. Additionally, new §850.87 incorporates §850.111, relating to Appeal of Final Decision, concurrently proposed for repeal.

§850.89. Computation of Time

New §850.89 retains and re-letters the provisions of §850.84, relating to Computation of Time, and concurrently proposed for repeal, with modifications to update terminology.

SUBCHAPTER E. VOCATIONAL REHABILITATION SERVICES APPEALS AND HEARING PROCEDURES

TWC proposes the repeal of Subchapter E in its entirety. The relevant portions of this content are consolidated with related content repealed in other subchapters and reorganized as proposed new Subchapter E.

Division 1. General Rules

§850.60 Purpose

§850.61 Legal Authority

§850.62 Definitions

§850.63 Filing a Request for Review

§850.64 Time for Hearing

§850.65 Assignment of Impartial Hearing Officer

§850.66 Powers and Duties of Impartial Hearing Officer

§850.67 Substitution of Impartial Hearing Officer

§850.68 Reasonable Accommodations

§850.69 Appearance of Parties at Hearings; Representation

§850.70 Failure to Attend Hearing and Default

§850.71 Witness Fees

§850.72 Prehearing Conferences

§850.73 Dismissal Without Hearing

§850.74 Conduct of Hearing

§850.75 Order of Proceedings

§850.76 Rules of Evidence

§850.77 Transcription of Proceedings

§850.78 Prepared Testimony

§850.79 Pleadings

§850.80 Continuance

§850.81 Motion for Reconsideration

§850.82 Civil Action

§850.83 Mediation Procedures

§850.84 Computation of Time

Division 2. Division for Blind Services and Division for Rehabilitation Services

§850.100 Purpose

§850.101 Legal Authority

§850.102 Definitions

§850.103 Filing a Request for Review

§850.104 Filings

§850.105 Discovery and Mandatory Disclosures

§850.106 Documentary Evidence and Official Notice

§850.107 Impartial Hearing Officer Decision

§850.108 Finality of the Hearing Officer's Decision

§850.109 Implementation of Final Decision

§850.110 Motion for Reconsideration

§850.111 Appeal of Final Decision

SUBCHAPTER F. MEMORANDUM OF UNDERSTANDING

TWC proposes the following amendments to Subchapter F:

§850.130. Memorandum of Understanding Regarding Continuity of Care for Physically Disabled Inmates

Section 850.130 is amended to replace references to "DARS" with "Agency," and update citations and titles.

§850.131. Memorandum of Understanding Regarding the Exchange and Distribution of Public Awareness Information

Section 850.131 is amended to replace references to "DARS" with "Agency," update agency names, and update citations.

§850.132. Memorandum of Understanding Concerning Coordination of Services to Disabled Persons

Section 850.132 is amended to remove references to DARS, update agency names, and update citations and terminology.

PART III. IMPACT STATEMENTS

Randy Townsend, Chief Financial Officer, has determined that for each year of the first five years the rules will be in effect, the following statements will apply:

There are no additional estimated costs to the state and to local governments expected as a result of enforcing or administering the rules.

There are no estimated cost reductions to the state and to local governments as a result of enforcing or administering the rules.

There are no estimated losses or increases in revenue to the state or to local governments as a result of enforcing or administering the rules.

There are no foreseeable implications relating to costs or revenue of the state or local governments as a result of enforcing or administering the rules.

There are no anticipated economic costs to individuals required to comply with the rules.

There is no anticipated adverse economic impact on small businesses, microbusinesses, or rural communities as a result of enforcing or administering the rules.

Based on the analyses required by Texas Government Code §2001.024, TWC has determined that the requirement to repeal or amend a rule, as required by Texas Government Code §2001.0045, does not apply to this rulemaking. Additionally, Texas Labor Code §352.101 requires TWC's three-member Commission (Commission) to adopt rules necessary to integrate the VR programs, including recommending adopting rules to implement the integration. Therefore, the exception identified in §2001.0045(c)(9) applies.

Takings Impact Assessment

Under Texas Government Code, §2007.002(5), "taking" means a governmental action that affects private real property, in whole or in part or temporarily or permanently, in a manner that requires the governmental entity to compensate the private real property owner as provided by the Fifth and Fourteenth Amendments to the United States Constitution or the Texas Constitution, §17 or §19, Article I, or restricts or limits the owner's right to the property that would otherwise exist in the absence of the governmental action, and is the producing cause of a reduction of at least 25 percent in the market value of the affected private real property, determined by comparing the market value of the property as if the governmental action is not in effect and the market value of the property determined as if the governmental action is in effect. The Commission completed a Takings Impact Analysis for the proposed rulemaking action under Texas Government Code, §2007.043. The primary purpose of this proposed rulemaking action, as discussed elsewhere in this preamble, is to align Chapter 850 with TWC's operation of the VR services program.

The proposed rulemaking action will not create any additional burden on private real property. The proposed rulemaking action will not affect private real property in a manner that would require compensation to private real property owners under the United States Constitution or the Texas Constitution. The proposal also will not affect private real property in a manner that restricts or limits an owner's right to the property that would otherwise exist in the absence of the governmental action. Therefore, the proposed rulemaking will not cause a taking under Texas Government Code, Chapter 2007.

Government Growth Impact Statement

TWC has determined that during the first five years the amendments will be in effect:

--the proposed amendments will not create or eliminate a government program;

--implementation of the proposed amendments will not require the creation or elimination of employee positions;

--implementation of the proposed amendments will not require an increase or decrease in future legislative appropriations to TWC;

--the proposed amendments will not require an increase or decrease in fees paid to TWC;

--the proposed amendments will not create a new regulation;

--the proposed amendments will not expand, limit, or eliminate an existing regulation;

--the proposed amendments will not change the number of individuals subject to the rules; and

--the proposed amendments will not positively or adversely affect the state's economy.

Economic Impact Statement and Regulatory Flexibility Analysis

TWC has determined that the rules will not have an adverse economic impact on small businesses or rural communities, as these rules place no requirements on small businesses or rural communities.

Mariana Vega, Director of Labor Market and Career Information, has determined that there is no significant negative impact upon employment conditions in the state as a result of the rules.

Cheryl Fuller, Director, Vocational Rehabilitation Division, has determined that for each year of the first five years the rules are in effect, the public benefit anticipated as a result of enforcing the rules will be to align Chapter 850 with TWC's operation of the VR services program.

PART IV. COORDINATION ACTIVITIES

In the development of these rules for publication and public comment, TWC sought the involvement of Texas' 28 Boards. TWC provided the concept paper regarding these rule amendments to the Boards for consideration and review on June 14, 2018. TWC also conducted a conference call with Board executive directors and Board staff on June 22, 2018, to discuss the concept paper. During the rulemaking process, TWC considered all information gathered in order to develop rules that provide clear and concise direction to all parties involved.

Comments on the proposed rules may be submitted to TWC Policy Comments, Workforce Policy and Service Delivery, attn: Workforce Editing, 101 East 15th Street, Room 459T, Austin, Texas 78778; faxed to (512) 475-3577; or e-mailed to TWCPolicyComments@twc.state.tx.us. Comments must be received or postmarked no later than 30 days from the date this proposal is published in the *Texas Register*.

SUBCHAPTER A. VOCATIONAL REHABILITATION GENERAL RULES

40 TAC §§850.1, 850.2, 850.7 - 850.10

The repeals are proposed under the authority of the Rehabilitation Act of 1973, as amended (29 USC §701 et seq.), and

regulations of the U.S. Department of Education, 34 CFR Parts 361, 363, 367, 395, and 397. Texas Labor Code §352.101(b)(5) requires TWC to recommend the adoption of any rules necessary to implement the requirement to integrate the VR programs. Texas Labor Code §301.0015 and §302.002(d) provide TWC with the authority to adopt, amend, or repeal such rules as it deems necessary for the effective administration of TWC services and activities.

The proposed repeals affect Title 4, Texas Labor Code, Chapters, 301, 302, 352, and 355.

§850.1. Purpose.

§850.2. Legal Authority.

§850.7. Criminal History Information on Applicants for Employment.

§850.8. Use of Criminal History Information in Contracting.

§850.9. Fees for Department Publications.

§850.10. Gifts and Donations to TWC.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Jason Vaden
Director, Workforce Program Policy
Texas Workforce Commission
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For further information, please call: (512) 689-9855

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40 TAC §§850.3 - 850.6, 850.11

The rules are proposed under the authority of the Rehabilitation Act of 1973, as amended (29 USC §701 et seq.), and regulations of the U.S. Department of Education, 34 CFR Parts 361, 363, 367, 395, and 397. Texas Labor Code §352.101(b)(5) requires TWC to recommend the adoption of any rules necessary to implement the requirement to integrate the VR programs. Texas Labor Code §301.0015 and §302.002(d) provide TWC with the authority to adopt, amend, or repeal such rules as it deems necessary for the effective administration of TWC services and activities.

The proposed rules affect Title 4, Texas Labor Code, Chapters, 301, 302, 352, and 355.

§850.3. Definitions.

The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise:

~~[(1) DARS--The Texas Department of Assistive and Rehabilitative Services.]~~

(1) ~~[(2)]~~ Counselor--An Agency ~~[A DARS]~~ employee who is trained to provide vocational guidance and counseling and meets the minimum qualifications designated in a functional job description.

(2) ~~[(3)]~~ State Plan--The plan for vocational rehabilitation services submitted by the Vocational Rehabilitation Division (VRD) ~~[the DARS Division for Rehabilitation Services and the DARS Division for Blind Services]~~ in compliance with Title I of the Rehabilitation Act of 1973, as amended[~~, Title I~~].

§850.4. Opportunities for Citizen Participation.

In addition to other procedures listed in Part 2 of this title (relating to Department of Assistive and Rehabilitative Services), individuals ~~[people]~~ with disabilities, parents of infants and toddlers with disabilities, and other citizens have the opportunity to:

(1) voice concerns through public representation on Agency ~~[DARS]~~ committees, councils, and boards;

(2) attend and make public comments at public meetings (notices of all public meetings and agenda items are published in the *Texas Register);*

(3) comment on all proposed rules; and

(4) submit a petition requesting the adoption of rules.

(A) All petitions proposing the adoption of Agency ~~[DARS]~~ rules shall be submitted in writing to the Commission ~~[DARS commissioner]~~. The petition must contain the following:

(i) the text of the proposed rule prepared in a manner to indicate the words to be added or deleted from the current text, if any;

(ii) a statement of the statutory or other authority under which the rule is to be promulgated; and

(iii) the public benefits anticipated as a result of adopting the rule or the anticipated implications that could result from the failure to adopt the proposed rule.

(B) Agency ~~[DARS]~~ staff reviews ~~[members review]~~ the requests and present recommendations to the Commission ~~[DARS]~~ for action.

§850.5. Complaints.

(a) Complaints may be filed with the Agency ~~[DARS]~~ either in writing through mail, e-mail, or facsimile or by videotape for individuals ~~[people]~~ who use sign language to communicate. Complaints should be directed to the customer's local VR office or may be submitted via email to customers@twc.state.tx.us. ~~[DARS customer service representative or to the commissioner.]~~

(b) For the purpose of directing complaints to the Agency, the Agency ~~[DARS, DARS]~~ may notify customers ~~[consumers]~~ and service recipients of its name, mailing address, and telephone number by including the information:

(1) on each registration form, application, or written contract relating to participation in a program that is funded in any part by money derived from or through the Agency ~~[DARS]~~;

(2) on a sign that is prominently displayed in the place of business of each individual ~~[person]~~ or entity engaging in a program that is funded in any part by money derived from or through the Agency ~~[DARS]~~;

(3) in a bill for service provided by an individual ~~[a person]~~ or entity engaging in a program that is funded in any part by money derived from or through the Agency ~~[DARS]~~; or

(4) in other media for dissemination of information as determined by the Agency ~~[DARS]~~.

(c) Ordinarily, the Agency ~~[DARS]~~ resolves complaints within 60 days.

~~[(d) Information about complaints specifically related to early childhood intervention services may be found in Chapter 108 of this title (relating to Division for Early Childhood Intervention Services).]~~

~~[(e) Information about complaints specifically related to Blind Children's Vocational Discovery and Development Program may be~~

~~found in Chapter 106 of this title (relating to Division for Blind Services).~~]

§850.6. Cooperation with Other Public Agencies.

The Agency [~~DARS~~] enters into appropriate cooperative arrangements with, and uses the services and facilities of, other federal, state, and local public agencies providing services related to rehabilitation of individuals [~~people~~] with disabilities. The Agency [~~DARS~~] also works toward maximum coordination and consultation with programs for and relating to rehabilitation of veterans with disabilities.

§850.11. Qualified Vocational Rehabilitation Counselor [~~Vocational Rehabilitation Counselor (QVRC)~~].

(a) The Vocational Rehabilitation Division (VRD) helps [~~Division for Rehabilitation Services (DRS) and Division for Blind Services (DBS) help~~] counselors to meet the Comprehensive System of Personnel Development (CSPD) standard by making funds available through the Qualified Vocational Rehabilitation Counselor (QVRC) program for the required graduate education except when:

(1) unforeseen circumstances occur that may restrict or prohibit the funding; or

(2) management discontinues a counselor's participation in the program in the best interests of the division.

(b) The VRD director [~~regional director (DRS), director of program management (DBS),~~] or designee must approve QVRC financial assistance. This financial assistance is contingent on:

(1) funding;

(2) management approval; and

(3) compliance with qualifications for participation.

(c) Qualifications for participation in the QVRC program [~~Program~~] require that vocational rehabilitation counselors, transition vocational rehabilitation counselors, VRD vocational rehabilitation coordinators [~~(DBS)~~] or VRD unit program specialists [~~(DRS)~~] applying for assistance must:

(1) have completed the initial training year;

(2) be meeting or exceeding job performance expectations;

(3) obtain the appropriate approvals to pursue a graduate degree or prescribed coursework;

(4) apply for Rehabilitation Services Administration (RSA) scholarship and university stipend funding; and

(5) be accepted by the appropriate institution of higher education.

(d) A counselor who meets the CSPD standard is considered a Qualified Vocational Rehabilitation Counselor.

(e) A counselor is expected to meet the CSPD standard within seven years from completion of the initial training year. Divisions must conduct transcript reviews and/or confirm certifications to determine compliance with standards or to outline coursework to be completed by the counselor.

(f) A counselor is expected to pay all costs or expenses:

(1) associated with the college application and admission except one GRE fee;

(2) related to tuition, fees, and books for any coursework that must be repeated because of failure to successfully complete; and

(3) related to completing work necessary to remove any grade of "I" (Incomplete) within three months, unless there are valid reasons (for example, serious illness, or university regulations to the contrary).

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Texas Workforce Commission
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SUBCHAPTER B. HISTORICALLY UNDERUTILIZED BUSINESSES

40 TAC §§850.20 - 850.23

The repeals are proposed under the authority of the Rehabilitation Act of 1973, as amended (29 USC §701 et seq.), and regulations of the U.S. Department of Education, 34 CFR Parts 361, 363, 367, 395, and 397. Texas Labor Code §352.101(b)(5) requires TWC to recommend the adoption of any rules necessary to implement the requirement to integrate the VR programs. Texas Labor Code §301.0015 and §302.002(d) provide TWC with the authority to adopt, amend, or repeal such rules as it deems necessary for the effective administration of TWC services and activities.

The proposed repeals affect Title 4, Texas Labor Code, Chapters, 301, 302, 352, and 355.

§850.20. Purpose.

§850.21. Legal Authority.

§850.22. Definitions.

§850.23. Adoption of Rules.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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SUBCHAPTER C. COUNCILS, BOARD, AND COMMITTEES

DIVISION 1. REHABILITATION COUNCIL OF TEXAS

40 TAC §850.30, §850.31

The repeals are proposed under the authority of the Rehabilitation Act of 1973, as amended (29 USC §701 et seq.), and regulations of the U.S. Department of Education, 34 CFR Parts 361, 363, 367, 395, and 397. Texas Labor Code §352.101(b)(5) requires TWC to recommend the adoption of any rules necessary to implement the requirement to integrate the VR programs. Texas Labor Code §301.0015 and §302.002(d) provide TWC with the authority to adopt, amend, or repeal such rules as it deems necessary for the effective administration of TWC services and activities.

The proposed repeals affect Title 4, Texas Labor Code, Chapters, 301, 302, 352, and 355.

§850.30. Purpose.
§850.31. Legal Authority.
The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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40 TAC §§850.32 - 850.35

The rules are proposed under the authority of the Rehabilitation Act of 1973, as amended (29 USC §701 et seq.), and regulations of the U.S. Department of Education, 34 CFR Parts 361, 363, 367, 395, and 397. Texas Labor Code §352.101(b)(5) requires TWC to recommend the adoption of any rules necessary to implement the requirement to integrate the VR programs. Texas Labor Code §301.0015 and §302.002(d) provide TWC with the authority to adopt, amend, or repeal such rules as it deems necessary for the effective administration of TWC services and activities.

The proposed rules affect Title 4, Texas Labor Code, Chapters, 301, 302, 352, and 355.

§850.32. Definitions.
The following words and terms, when used in this division, have the following meanings, unless the context clearly indicates otherwise:

(1) Agency [~~DARS~~]--The Texas Workforce Commission [~~Department of Assistive and Rehabilitative Services~~].

(2) RCT--The Rehabilitation Council of Texas.

[~~(3) Divisions--The DARS Division for Rehabilitation Services (DRS) and the DARS Division for Blind Services (DBS).~~]

§850.33. Tasks.
Tasks. The RCT [~~council~~] shall:

(1) review, analyze, and advise the VRD [~~divisions~~] about their performance of responsibilities, particularly those relating to:

(A) eligibility determination (including order of selection);

(B) the extent, scope, and effectiveness of services provided; and

(C) functions performed by VRD [~~the divisions~~] that potentially affect the ability of individuals [~~people~~] with disabilities to achieve rehabilitation goals and objectives;

(2) advise the Vocational Rehabilitation Division (VRD) [~~divisions~~] and, at its discretion, help [~~helps~~] prepare the State Plan for Vocational Rehabilitation Services; amendments to the plan; and applications, reports, needs assessments, and evaluations required;

(3) to the extent feasible, review and analyze the effectiveness of, and customer [~~consumer~~] satisfaction with:

(A) the functions performed by state agencies and other public and private entities responsible for performing functions for individuals [~~people~~] with disabilities; and

(B) vocational rehabilitation services:

(i) provided, or paid for from funds made available, under 29 USC [~~United States Code~~] §725, or through other public or private sources; and

(ii) provided by state agencies and other public and private entities responsible for providing vocational rehabilitation services to individuals [~~people~~] with disabilities; and

(C) the employment outcomes achieved by individuals [~~people~~] who receive services under 29 USC [~~United States Code~~] §725, including the availability of health and other employment benefits in connection with those employment outcomes;

(4) coordinate with other councils in the state, including the State Independent Living Council established under 29 USC [~~United States Code~~] §796d; the advisory panel established under §612(a)(20) of the Individuals with Disabilities Education Act 20 USC [~~U.S.C.~~] §1412(a)(21); the State Council on Developmental Disabilities described in 42 USC [~~United States Code~~] §15025; the State Mental Health Planning Council established under 42 USC [~~United States Code~~] §300x-3(a); and the state workforce investment board;

(5) advise VRD [~~the divisions~~] and coordinate [~~coordinates~~] working relationships between the divisions and the State Independent Living Council and centers for independent living within the state; and

(6) perform other comparable functions consistent with the Rehabilitation Act of 1973, as amended, that the RCT [~~RTC~~] determines to be appropriate.

§850.34. Reports.

The RCT [~~Rehabilitation Council of Texas (RCT)~~] shall:

(1) prepare and submit an annual report to the governor or appropriate state entity and the Commission [~~commissioner~~] on the status of vocational rehabilitation programs operated within the state, and make the report available to the public; and

(2) submit to the commissioner of the Rehabilitation Services Administration, United States Department of Education, periodic reports that the commissioner may reasonably request, and keep records that the commissioner finds necessary to verify those reports.

§850.35. Funding.

The Rehabilitation Council of Texas (RCT) is funded primarily by federal funds, and its existence is required in order for the Agency [~~DARS~~] to receive and expend federal funds.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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DIVISION 2. BET ELECTED COMMITTEE OF MANAGERS (ECM)

40 TAC §§850.40 - 850.43

The repeals are proposed under the authority of the Rehabilitation Act of 1973, as amended (29 USC §701 et seq.), and regulations of the U.S. Department of Education, 34 CFR Parts 361, 363, 367, 395, and 397. Texas Labor Code §352.101(b)(5) requires TWC to recommend the adoption of any rules necessary to implement the requirement to integrate the VR programs. Texas Labor Code §301.0015 and §302.002(d) provide TWC with the authority to adopt, amend, or repeal such rules as it deems necessary for the effective administration of TWC services and activities.

The proposed repeals affect Title 4, Texas Labor Code, Chapters, 301, 302, 352, and 355.

§850.40. Purpose.
§850.41. Legal Authority.
§850.42. Definitions.
§850.43. Substantive Rules.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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SUBCHAPTER D. PRIVACY AND CONFIDENTIALITY

40 TAC §850.50, §850.51

The rules are proposed under the authority of the Rehabilitation Act of 1973, as amended (29 USC §701 et seq.), and regulations of the U.S. Department of Education, 34 CFR Parts 361, 363, 367, 395, and 397. Texas Labor Code §352.101(b)(5) requires TWC to recommend the adoption of any rules necessary to implement the requirement to integrate the VR programs. Texas Labor Code §301.0015 and §302.002(d) provide TWC with the authority to adopt, amend, or repeal such rules as it deems necessary for the effective administration of TWC services and activities.

The proposed rules affect Title 4, Texas Labor Code, Chapters, 301, 302, 352, and 355.

§850.50. Privacy Policies.

In accordance with Chapter 559, Government Code, the Agency [~~DARS~~] adheres to the following privacy policies.

(1) Right to be informed about information collected. An individual [~~A person~~] has the right to be informed about information that the Agency [~~DARS~~] collects about the individual [~~person~~] unless the Agency [~~DARS~~] is allowed to withhold the information from the individual [~~person~~] under Government Code, §552.023(b).

(2) Right to receive notice about certain information laws and practices.

(A) When the Agency [~~DARS~~] collects information about an individual [~~a person~~] by means of a form that the individual [~~person~~] completes and files with the Agency, the Agency [~~DARS, DARS~~] informs the individual [~~person~~] of his or her rights related to the information collected. If the form is in a paper format, the Agency [~~DARS~~] posts a prominent notice of the individual's [~~person's~~] rights on the form. Or if the form is in an electronic format on an Internet site, the Agency [~~DARS~~] prominently posts the notice on the Internet site in connection with the electronic form. The notice states that:

(i) with few exceptions, the individual [~~person~~] is entitled on request to be informed about the information that the Agency [~~DARS~~] collects about the individual [~~person~~];

(ii) under the Government Code, §552.021 and §552.023, the individual [~~person~~] may receive and review the information; and

(iii) under the Government Code, §559.004, the individual [~~person~~] may have the Agency [~~DARS~~] correct information about the individual [~~person~~] that is incorrect.

(B) When Agency staff [~~DARS~~] uses an Internet site to collect information about an individual [~~a person~~] or about the computer network location or identity of a user of the site, the Agency [~~DARS~~] prominently posts on the site what information the Agency [~~DARS~~] is collecting, including such information being collected by means that are not obvious.

(3) Right to correction of incorrect information. The Agency [~~DARS~~] has established a procedure under which an individual [~~a person~~] may have the Agency [~~DARS~~] correct information that the Agency [~~DARS~~] possesses about the individual [~~person~~] and that is incorrect. The individual [~~person~~] should send a written request to the Agency [~~DARS~~], including his or her full name and mailing address; identify the incorrect information; and provide the correct information. If the information to be corrected is related [~~to a social security disability determination,~~] to a vocational rehabilitation case, or to an Agency [~~a DARS~~] personnel or employment record, documentation establishing the individual's identity [~~person's social security number~~] should be included. The individual [~~person~~] should attach to the request any additional material needed to identify the incorrect information or verify the correct information. The individual should [~~person may choose to~~] include with the request contact information such as address, a daytime telephone number and an email address in case the Agency [~~DARS~~] needs to [~~call to~~] clarify the request. The individual [~~person~~] must sign and mail the request to Records Management Center [~~Department of Assistive and Rehabilitative Services~~], ATTN: Records Management Officer, 4405A Springdale Road [~~Office, 4900 North Lamar Boulevard~~], Austin, Texas 78723-6050 [~~78751-2316~~]. The Agency [~~DARS~~] will acknowledge receipt of the request, and will notify the individual [~~person~~] of final action taken.

(4) Applicability of Public Information Law. Government Code, Chapter 552, governs the charges that the Agency [~~DARS~~] may impose on an individual [~~a person~~] who requests information that the Agency [~~DARS~~] collects about himself or herself. However, the Agency [~~DARS~~] does not charge an individual [~~a person~~] to correct information about the individual [~~person~~].

§850.51. Confidentiality of Customer [~~Consumer~~] Information in Vocational Rehabilitation Services Program.

(a) Customer [~~Consumer~~] records.

(1) All personal information available to Agency [~~DARS~~] employees as they administer rehabilitation services programs, including names, addresses, and records of customer [~~consumer~~] evaluations, is confidential.

(2) The Agency [~~DARS~~] may use such information and records only for purposes directly connected with administering the vocational rehabilitation programs.

(3) The Agency [~~DARS~~] may directly or indirectly disclose information only in administering the rehabilitation programs, except with the customer's [~~consumer's~~] written consent, in compliance with a court order, or in accordance with a federal or state law or regulation. The Agency [~~DARS~~] may not share information containing identifiable personal information with advisory or other bodies that do not have official responsibilities for administration of the programs.

(4) Upon a customer's [~~consumer's~~] request, the Agency [~~DARS~~] releases information to the customer [~~a consumer~~] or, as appropriate, his or her parent, guardian, or other representative. If, in the opinion of the counselor, release to the customer [~~consumer~~] of a particular document in the customer [~~consumer~~] case file will have a harmful effect on the customer [~~consumer~~], the customer [~~consumer~~] will be notified that there is information in the case file that can be released only to an appropriate representative designated in writing by the customer [~~consumer~~].

(5) All customer [~~consumer~~] information is the property of the Agency [~~DARS~~].

(b) Other records.

(1) Release of customer [~~consumer~~] records must be made in accordance with federal law and regulations.

(2) The Agency [~~DARS~~] may provide to and receive from any state agency other nonconfidential information for the purpose of increasing and enhancing services to customers [~~consumer~~] and improving agency operations.

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SUBCHAPTER E. VOCATIONAL REHABILITATION SERVICES APPEALS AND HEARING PROCEDURES

40 TAC §§850.60 - 850.89

The new rules are proposed under the authority of the Rehabilitation Act of 1973, as amended (29 USC §701 et seq.), and regulations of the U.S. Department of Education, 34 CFR Parts 361, 363, 367, 395, and 397. Texas Labor Code §352.101(b)(5) requires TWC to recommend the adoption of any rules necessary to implement the requirement to integrate the VR programs. Texas Labor Code §301.0015 and §302.002(d) provide TWC with the authority to adopt, amend, or repeal such rules as it deems necessary for the effective administration of TWC services and activities.

The proposed new rules affect Title 4, Texas Labor Code, Chapters, 301, 302, 352, and 355.

§850.60. Scope.

(a) The following statutes and regulations authorize the procedures established by this chapter:

(1) The Rehabilitation Act of 1973, as amended, 29 USC §701 et seq. and regulations of the U.S. Department of Education, Rehabilitation Services Administration, 34 CFR Part 361, as amended, relating to State Vocational Rehabilitation Services;

(2) 34 CFR Part 395, as amended, relating to Vending Facility Program for the Blind on Federal and Other Property; and

(3) 34 CFR Part 367, as amended, relating to Independent Living Services for Older Individuals Who Are Blind (ILS-OIB).

(b) The procedures in this subchapter apply to those determinations made by Agency personnel that affect the provision of vocational rehabilitation (VR) services, independent living services for older individuals who are blind, and the Business Enterprises of Texas program.

(1) Unless the determination concerns the denial, reduction, suspension, or termination of VR services, independent living services for older individuals who are blind, or comprehensive rehabilitation services by the Agency, it is not subject to review under the procedures of this subchapter.

(2) The following decisions or determinations are not subject to review under this subchapter:

(A) administrative decisions that are made by Agency supervisors or managers without reference to any specific applicant or customer and that apply generally to the provision of VR services to applicants or customers, including to decisions concerning the assignment of personnel;

(B) decisions, diagnoses, judgments, actions, or omissions of third-party vendors or service providers;

(C) decisions concerning the content of an applicant's or customer's record of service for which remedies are provided under 34 CFR §361.38(c)(4) and §361.47(a)(12); and

(D) decisions allegedly violating any state or federal antidiscrimination or civil rights statute (as amended), including the provisions of Texas Labor Code, Chapter 21; the Rehabilitation Act of 1973, as amended; Section 504, the Americans with Disabilities Act; or the Age Discrimination in Employment Act.

(c) Ineligibility. The following may challenge a determination of ineligibility through the procedures of this division:

(1) applicants who are found not to be eligible for VR services; and

(2) previously eligible individuals who have been determined no longer eligible for VR services under 34 CFR §361.43.

(d) An individual's decision to seek an informal resolution of matters about which the individual is dissatisfied shall not prevent, compromise, or delay the individual's access to formal resolution procedures in this division.

(e) The Agency shall not suspend, reduce, or terminate VR services being provided to an applicant or customer, including evaluation and assessment services and the development of an Individualized Plan for Employment, pending a resolution of the applicant's or customer's appeal by mediation or hearing, unless:

(1) the applicant or customer requests a suspension, reduction, or termination of services; or

(2) the Agency has evidence that the applicant or customer obtained the services through misrepresentation, fraud, collusion, or criminal conduct.

§850.61. Definitions.

The following words and terms, when used in this subchapter, have the following meanings unless the context clearly indicates otherwise. The use of the singular or plural case is not meant to be limiting unless the context clearly indicates otherwise.

(1) Act--The Rehabilitation Act of 1973 as amended, 29 USC §701, et seq.

(2) Appellant--An applicant, eligible individual, authorized representative, or parent who has initiated formal procedures under this subchapter.

(3) Applicant--An individual who submits an application for VR services in accordance with 34 CFR Part 361.

(4) Authorized representative--An attorney authorized to practice law in the State of Texas, or an individual designated by a party to represent the party in hearing procedures. The term includes a parent or an individual made legally responsible for a child by a court of competent jurisdiction.

(5) Counselor--An Agency employee who is trained to provide vocational guidance and counseling and meets the minimum qualifications designated in a functional job description.

(6) Customer--An applicant or an individual with a disability who is receiving VR services.

(7) Discovery--The process by which a party, before any final hearing on the merits, may obtain evidence and other information that is relevant to a claim or defense in the appeal.

(8) Eligible individual--Any individual with a disability determined to be eligible to receive VR services.

(9) Hearing--A formal review conducted under this chapter. This term includes prehearing conferences.

(10) Impartial hearing officer (IHO)--An individual who is appointed to conduct a hearing under this chapter.

(11) Individualized Plan for Employment--A plan developed for each individual determined to be eligible for VR services, in accordance with 34 CFR Part 361.

(12) Parent--The term "parent," whether singular or plural, means a minor child's natural or adoptive parent, the spouse of the minor child's natural or adoptive parent, the minor child's surrogate or foster parent, the spouse of the surrogate or foster parent, or other individual made legally responsible for the minor child by a court.

(13) Party--An individual or agency named or admitted to participate in a formal hearing.

(14) Record--The official record of a hearing, including all arguments, briefs, pleadings, motions, intermediate rulings, orders, evidence received or considered, statements of matters officially noticed, questions and offers of proof, objections and rulings on objections, proposed findings of fact, conclusions of law, and hearing officer decision; any other decision, opinion, or report by the hearing officer or Commission; and all memoranda or data, including customer and applicant files, submitted to or considered by the impartial hearing officer.

(15) State Plan--The plan for VR services submitted by the Agency's Vocational Rehabilitation Division in compliance with the Act.

§850.62. Filing a Request for Review.

(a) Any applicant or eligible individual who is dissatisfied with a determination made by the Agency, as described in §850.60 of this subchapter (relating to Scope), may request, or, if appropriate, may request through the individual's authorized representative, a review of the determination. Although no prescribed form is required to file a request, preprinted forms for this purpose are available on request at any Agency VR office.

(b) The request for a review shall be filed in writing with the hearings coordinator within the Agency's Office of General Counsel.

(1) A request shall be considered filed on the day that it is received by the hearings coordinator within the Agency's Office of General Counsel.

(2) Preprinted forms for this purpose are available on request from the hearings coordinator within the Agency's Office of General Counsel or any Agency VR office.

(c) On receiving a request for review, the hearings coordinator within the Agency's Office of General Counsel shall, within five working days, mail the appellant:

(1) the name, address, and telephone number of the Client Assistance Program established under federal law;

(2) the name of the IHO appointed to hear the appeal, and the date, time, and place of any prehearing;

(3) a copy of applicable hearing procedures; and

(4) notice that the appellant has the right to request mediation procedures.

§850.63. Informal Dispute Resolution.

(a) The Agency shall provide an opportunity for informal resolution of an appeal.

(b) Informal resolution may include, but is not limited to:

(1) informal meetings with VR counselors or their supervisors;

(2) second reviews of the case file and case decisions by VR management;

(3) telephone calls to or conference calls that include the affected parties; or

(4) written explanations or summaries of the policies, laws, or regulations involved in the complaint.

(c) If the informal resolution procedure results in a final agreement between the parties, no hearing shall be held.

(d) If no final informal resolution is reached, the Agency shall provide an opportunity for a hearing to resolve an appeal.

(e) Either a final agreement resulting from informal resolution or a hearing and impartial hearing officer decision shall be completed within 60 calendar days of the original filing of the appeal, unless the parties agree to a specific extension of time.

§850.64. Time for Hearing.

A hearing conducted under this chapter by an IHO selected in accordance with §850.65 of this subchapter (relating to Mediation Procedures), will be held within 60 days of an applicant's or eligible individual's request for review of an Agency determination that affects the provision of VR services to the individual, unless informal resolution or a mediation agreement is achieved before the 60th day or the parties agree to a specific extension of time.

§850.65. Mediation Procedures.

(a) An applicant or eligible individual who has initiated a proceeding under this subchapter, may request, or may request through the individual's authorized representative, mediation to resolve the dispute. The Agency, with the consent of the applicant, eligible individual, or the authorized representative, as appropriate, may also originate the request for mediation.

(b) Mediation is voluntary on the part of the parties. At any point during the mediation process, either party or the mediator may elect to terminate the mediation. In the event that mediation is terminated, either party may pursue resolution through an impartial hearing. Mediation shall not be used to deny or delay the right of an individual to a hearing under this subchapter, or to deny any other right afforded by the Act. Mediation shall be conducted by a qualified and impartial mediator who is trained in effective mediation techniques.

(c) The Agency shall bear all costs related to the mediation process, consistent with this subchapter.

(d) The request for mediation shall be filed in writing with the hearings coordinator within the Agency's Office of General Counsel. On receiving a request for mediation from the parties, the hearings coordinator shall randomly select an individual from a list of qualified mediators who are knowledgeable in laws and regulations relating to the provision of VR services, ILS-OIB, or the Business Enterprises of Texas program, whichever may apply to the dispute.

(e) Sessions in the mediation process shall be coordinated by the mediator in a timely manner at a location convenient to both parties in the dispute. Parties shall be provided an opportunity to submit evidence and other information that supports their positions.

(f) All discussions that occur during the mediation sessions are confidential and shall not be used as evidence in any subsequent due process hearing or civil proceeding. The mediator may require the parties to sign a confidentiality pledge before the start of the mediation process.

(g) Any agreement reached through the mediation process shall be documented in a written mediation agreement and signed by the parties to the dispute. Copies shall be provided to both parties. The agreement then becomes a part of the customer record.

§850.66. Assignment of Impartial Hearing Officer.

(a) The hearings coordinator, as described in §850.62 of this subchapter (relating to Filing a Request for Review), shall select, on a random basis, or by agreement between the Agency and the appellant, or if appropriate, the appellant's authorized representative or a parent, an IHO from a list of qualified IHOs maintained by the Agency.

(b) The IHO shall be an individual who:

(1) is not an employee of a public agency (other than an administrative law judge, hearing examiner, or employee of an institution of higher education);

(2) has knowledge of the delivery of VR services, the state plan, and the federal and state regulations governing appeals under this chapter;

(3) has received training specified by the Agency with respect to the performance of official duties; and

(4) has no personal, professional, or financial interest that would conflict with his or her objectivity in the hearing.

(c) An individual is not considered to be an employee of a public agency for the purposes of subsection (b) of this section solely because the individual is paid by the Agency to serve as a hearing officer.

(d) Despite the provisions in subsection (a) of this section, if in a subsequent appeal, the appellant raises factual issues or claims that were previously adjudicated or could have been adjudicated in a prior appeal:

(1) the hearings coordinator may appoint the same IHO that heard the prior appeal to hear the subsequent appeal; or

(2) the IHO, on Agency motion, reassigns the appeal to the IHO who heard the prior appeal.

§850.67. Powers and Duties of Impartial Hearing Officer.

(a) The IHO has the authority and duty to:

(1) conduct a full and impartial hearing;

(2) take action to avoid unnecessary delay in the disposition of the proceeding; and

(3) maintain order.

(b) The IHO has the power to regulate the course of the hearing, including the power to:

(1) administer oaths;

(2) take testimony;

(3) rule on questions of evidence;

(4) rule on discovery issues;

(5) issue orders relating to hearing and prehearing matters, including orders granting motions to subpoena witnesses and imposing nonmonetary sanctions regarding discovery;

(6) admit or deny party status;

(7) limit irrelevant, immaterial, and unduly repetitious testimony and reasonably limit the time for presentations;

(8) grant continuances;

(9) request parties to submit legal memoranda, proposed findings of fact, and conclusions of law; and

(10) issue decisions based on findings of fact and conclusions of law.

(c) Unless required for the disposition of ex parte matters authorized by law, the IHO shall not directly or indirectly communicate in connection with any issue of fact or law with any party or a party's authorized representative, except on notice and opportunity for each party to participate.

(d) Discovery conducted under subsection (b) of this section is subject to these rules and the Texas Administrative Procedure Act, Texas Government Code, Chapter 2001, Subchapter D.

§850.68. Substitution of Impartial Hearing Officer.

(a) If for any reason an IHO is unable to continue presiding over a pending hearing, or issue a decision after the conclusion of the hearing, another IHO shall be designated as a substitute to complete the hearing and render a decision in accordance with these rules. Reasons may include, but are not limited to, withdrawal or reassignment to avoid the appearance of impropriety or partiality.

(b) The substitute IHO may use the existing record and may conduct further proceedings as necessary and proper to conclude the hearing and render a decision.

§850.69. Reasonable Accommodations.

(a) Any hearing or proceedings conducted under this subchapter shall be held, whenever feasible, by telephone (directly or by relay), at a time and place reasonably accessible to the appellant and any witnesses, and convenient for parties. In considering the physical location of a hearing or proceeding, the IHO shall consider, among other factors:

(1) the suitability of any proposed facilities for a hearing, including the ability of the appellant and any witnesses to gain physical access to the proceedings and facilities; and

(2) the comparative distances and times required to travel from places of work or residence to a proposed hearing location by parties and witnesses.

(b) The Agency shall, upon reasonable notice, provide the appellant with readers or interpreters. Reasonable notice shall be considered to be no fewer than five working days prior to the proceeding, unless good cause for a shorter period exists in the judgment of the IHO.

(c) A copy of a transcript prepared during hearing proceedings and all notices and documents shall be provided to the appellant in an accessible format on request.

§850.70. Appearance of Parties at Hearings; Representation.

(a) An individual may represent himself or herself.

(b) A party may be represented by an attorney authorized to practice law in Texas or by any other representative authorized by the party to represent the party.

(c) A party's authorized representative shall be copied on all notices, pleadings, and other correspondence.

(d) A party's authorized representative remains the representative of record in absence of a formal request to withdraw and an order approving such withdrawal issued by the IHO.

(e) The Agency is not responsible for expenses incurred by appellants seeking remedy under this subchapter and representation and attorney fees and related expenses are the responsibility of the individual parties.

§850.71. Failure to Attend Hearing and Default.

If, after receiving notice of a hearing, a party or the party's authorized representative fails to attend the hearing, the IHO may proceed and, when appropriate, issue a default decision against the absent party.

§850.72. Witness Fees.

(a) Any witness or deponent who is not a party to, and who is subpoenaed or otherwise appears at, any hearing or proceeding at the request of the Agency is entitled to receive reimbursement as provided under Texas Government Code §2001.103.

(b) The Agency is not responsible for expenses incurred by any witness or deponent who is not a party to, and who is subpoenaed or otherwise appears at, any hearing or proceeding at the request of the appellant.

(c) The party calling or deposing an expert witness is responsible for all fees and expenses charged by the expert witness.

§850.73. Prehearing Conferences.

(a) The IHO may hold a prehearing conference to resolve matters preliminary to the hearing. At the discretion of the IHO, a prehearing conference may be held by telephone (directly or by relay). A prehearing conference may be convened to address any or all of the following matters:

(1) notice of jurisdiction or the IHO's authority;

(2) scope or party status;

(3) the date and location of the final hearing;

(4) factual and legal issues;

(5) motions;

(6) issuance of subpoenas;

(7) discovery disputes;

(8) scheduling;

(9) stipulations;

(10) settlement conferences;

(11) requests for official notice;

(12) identification and exchange of documentary evidence;

(13) admissibility of evidence;

(14) identification and qualification of witnesses;

(15) order of presentation; and

(16) other matters that promote the orderly and prompt conduct of the hearing.

(b) Within five business days of the date on which the IHO receives the appellant's petition or request for review, the IHO shall notify the appellant in writing of any other matters that the IHO considers expedient for an orderly conduct of the prehearing, including the following:

(1) the final or merits hearing will be held within 60 days after the date when the hearings coordinator received the petition or request for review;

(2) the appellant's right to request mediation;

(3) the reasons for the prehearing conference;

(4) the way the appellant might request a continuance of the prehearing conference;

(5) the effect of failing to participate in a prehearing conference; and

(6) the appellant's right to be represented.

§850.74. Dismissal without Hearing.

(a) The IHO may entertain motions for dismissal without a hearing for the following reasons:

(1) failure to pursue the hearing;

(2) unnecessary duplication of proceedings, res judicata, or collateral estoppel;

(3) withdrawal of the request for hearing;

(4) moot questions;

(5) lack of jurisdiction;

(6) failure to raise a material issue in the pleading;

(7) failure of a party or authorized representative to appear at a scheduled hearing;

(8) failure to respond to a discovery request; and

(9) failure to respond to any order by the IHO, including an order to disclose the identities of witnesses and exhibits.

(b) If the IHO finds that a motion for dismissal should be granted, he or she may enter a final order of dismissal.

§850.75. Conduct of Hearing.

(a) On a genuine issue in a contested case, each party or authorized representative is entitled to:

(1) call witnesses, including other parties;

(2) offer evidence;

(3) cross-examine any witness called by another party; and

(4) make opening and closing statements.

(b) Once the hearing has begun, the parties and authorized representatives shall only be off the record when the IHO permits. If the discussion off the record is pertinent, then the IHO summarizes the discussion for the record.

(c) Objections shall be noted in the record in a timely manner.

(d) The IHO may continue a hearing from time to time and from place to place. If the time and place for the hearing to reconvene are not announced at the hearing, a notice shall be mailed stating the time and place of the hearing.

(e) The IHO may question witnesses and parties and/or direct the submission of supplemental evidence.

§850.76. Order of Proceedings.

(a) A case shall be called to order by the IHO.

(b) Proceedings under this subchapter are conducted according to the following provisions:

(1) The appellant may briefly state the nature of the claim or defense, what the appellant expects to prove, and the relief sought. Immediately thereafter, the Agency may make a similar statement, and any other parties are afforded similar rights as determined by the IHO. The IHO may limit the time available for each party or authorized representative with respect to such statement.

(2) Evidence is introduced by the appellant. The Agency, or its authorized representative, and any other parties may cross-examine each of the appellant's witnesses.

(3) Cross-examination is not limited solely to matters raised on direct examination. Parties or authorized representatives are entitled to redirect and recross-examination.

(4) Unless the statement has already been made, the Agency or its authorized representative may briefly state the nature of the claim or defense, what the Agency expects to prove, and the relief sought.

(5) Evidence, if any, is introduced by the Agency. The appellant and any other parties may cross-examine each of the Agency's witnesses.

(6) Any other parties may make statements and introduce evidence. The appellant and the Agency may cross-examine the other parties' witnesses.

(7) The parties may present rebuttal evidence.

(8) The parties may be allowed to make either oral or written closing statements at the discretion of the IHO.

(9) The IHO may examine any witness and party.

(c) The IHO may permit deviations from this order of procedure in the interest of justice or to expedite the proceedings.

(d) Parties shall provide four copies of each exhibit offered.

(e) Burden of proof. The party seeking affirmative relief, either on the case as a whole or on an issue, bears the burden of proof to prove the affirmative of the issue, or the party's case as a whole, by a preponderance of the evidence.

§850.77. Rules of Evidence.

(a) The rules of evidence as applied in nonjury civil cases by the district courts of the State of Texas apply to a hearing under this subchapter.

(b) Exceptions--evidence inadmissible under the rules of evidence applied in nonjury civil cases by the district courts of the State of Texas may be admitted:

(1) if it consists of any documents contained in any Agency file related to the appellant; or

(2) if it is:

(A) necessary to ascertain the facts not reasonably susceptible of proof under those rules;

(B) not precluded by statute; and

(C) of a type on which reasonably prudent individuals commonly rely in the conduct of their affairs.

(c) Irrelevant, immaterial, or unduly repetitious evidence shall be excluded.

§850.78. Transcription of Proceedings.

(a) Unless precluded by law, the hearing shall be recorded electronically by tape recorder or similar device either by the IHO or by someone designated by the IHO. The recording is the official record of the testimony offered as evidence during the hearing. Any party, however, may request, at the party's expense, that the hearing be recorded by a court reporter if the request is made no later than 10 days before the date of the hearing.

(b) In lieu of a recording of the testimony electronically or of the reporting of testimony by a court reporter, the parties to a hearing may agree upon a statement of the evidence, agree to use recorded transcriptions as a statement of the testimonial evidence, or agree to the summarization of testimony before the IHO, provided, however, that proceedings or any part of them shall be transcribed on written request of any party.

(c) Unless otherwise provided in this subchapter, the party requesting a transcription of any electronic recording of the proceedings shall bear the cost for transcribing any such electronically recorded testimony. Nothing provided for in this section limits the Agency to a stenographic record of the proceedings.

§850.79. Prepared Testimony.

In all proceedings and after all parties of record have been given copies, the prepared testimony of a witness on direct examination may be in-

corporated in the record as if read or received as an exhibit. The prepared testimony may be in narrative or question-and-answer form. The witness shall be sworn and shall identify the testimony. The witness is subject to cross-examination, and the prepared testimony is subject to a motion to strike in whole or in part.

§850.80. Pleadings.

(a) In a formal appeal, all pleadings, for which no other form is prescribed, shall contain:

(1) the name of the party making the pleading;

(2) the names of all other known parties;

(3) a concise statement of the facts alleged and relied upon;

(4) a request stating the type of relief, action, or order desired;

(5) any other matter required by law;

(6) a certificate of service, as required by these rules; and

(7) the signature of the party or the party's authorized representative making the pleading.

(b) Any pleading filed in a formal appeal may be amended up to 14 days before the date of the hearing. Amendments filed after that time may be accepted at the discretion of the IHO.

(c) Any pleading may adopt and incorporate, by specific reference, any part of any document or entry in the official files and records of the Agency.

(d) All pleadings relating to any matter pending before the Agency shall be sent to Texas Workforce Commission, Office of General Counsel, 101 E. 15th Street, Room 608, Austin, Texas 78778-0001, with the notation "Attention: Hearings Coordinator," or delivered to the Agency at that address to be filed with the IHO and all parties.

(e) All pleadings shall be in a format and medium reasonably calculated to provide the required information and must be clear and legible.

(f) Pleadings shall contain the name, address, and telephone number of the party filing the document or the name, telephone number, and business address of the authorized representative.

(g) A certificate of service shall be contained in or attached to all filings. The certificate shall be signed by the individual making the filing, show the manner of service, state that the filing has been served on all other parties, and identify those parties. The certificate is prima facie evidence of service.

§850.81. Discovery and Mandatory Disclosures.

(a) Written Discovery. Requests for disclosure of information shall be the only form of written discovery that the parties are entitled to make. Unless a party is ordered by the IHO during a pretrial conference to disclose other information in addition to the items in this section, a party may request in writing that the other party disclose or produce the following:

(1) the names, addresses, and telephone numbers of individuals having knowledge of relevant facts, including those who might be called as witnesses and any expert who might be called to testify;

(2) for any testifying expert:

(A) the subject matter on which the expert will testify;

(B) the expert's summary; and

(C) a brief summary of the substance of the expert's mental impressions and opinions and the basis for them, along with all documents and tangible items reflecting such information;

(3) the issues and the factual basis for a party's claims and defenses in the appeal; and

(4) information concerning the appellant's employment, including the appellant's job application with the appellant's current employer and any personnel evaluations.

(b) Subject to the provisions in this section, parties may obtain discovery regarding any matter that is relevant to a claim or defense in the appeal.

(c) All discovery requests shall be directed to the party from which discovery is being sought.

(d) All disputes with respect to any discovery matter shall be filed with and resolved by the IHO.

(e) All parties shall be afforded a reasonable opportunity to file objections and motions to compel the IHO regarding any discovery requests.

(f) Copies of discovery requests and documents filed in response thereto shall be filed on all parties, but should not be filed with the IHO or the hearings coordinator unless directed to do so by the IHO or when in support of objections, motions to compel, motions for protective order, or motions to quash.

(g) Any documents contained in any Agency file that are related to the appellant are considered to be admissible. The Agency shall, without awaiting either an order or a discovery request under subsection (a) of this section, provide to the appellant a complete copy of the appellant's record of services, as described at 34 CFR §361.47, including any electronically stored or preserved records, to the extent pertinent to the determination that is the subject of the request for review.

§850.82. Documentary Evidence and Official Notice.

(a) Documentary evidence may be received in the form of copies or excerpts if the original is not readily available. On request, parties shall be given an opportunity to compare the original and the copy or excerpt.

(b) When numerous similar documents that are otherwise admissible are offered into evidence, the IHO may limit the documents received to those that are typical and representative. The IHO may also require that an abstract of relevant data from the documents be presented in the form of an exhibit, provided that all parties are given the right to examine the documents from which such abstracts were made.

(c) The following laws, rules, regulations, and policies are officially noticed:

(1) The Rehabilitation Act of 1973, as amended, 29 USC §701, et seq.;

(2) U.S. Department of Education regulations, 34 CFR Parts 361, 367, and 395;

(3) The Agency's State Plan for Vocational Rehabilitation Services;

(4) The Agency's Vocational Rehabilitation, Independent Living for Older Individuals Who Are Blind, and Rehabilitation policy manuals; and

(5) Texas Administrative Code, Title 40, Part 20, Texas Workforce Commission.

(d) Official notice also may be taken of:

(1) all facts that are judicially cognizable; and

(2) generally recognized facts within the area of the Agency's specialized knowledge.

§850.83. Continuance.

(a) The IHO, at his or her discretion, may grant a continuance to further the interests of justice. No motion for continuance shall be granted, unless it is made in writing or stated in the record, and the motion shall set forth the specific grounds upon which the party seeks the continuance.

(b) Unless made during a prehearing or hearing, a party seeking a continuance, cancellation of a scheduled proceeding, or extension of an established deadline shall file such motion no later than 10 days before the date or deadline in question. A motion filed fewer than 10 days before the date or deadline in question shall contain a certification that the requestor contacted the other party or party's authorized representative and whether the request is opposed by the party or party's authorized representative. Further, if a continuance to a certain date is sought, the motion shall include a proposed date or dates and must indicate whether the other party or party's authorized representative contacted agrees on the proposed new date or dates.

§850.84. Impartial Hearing Officer Decision.

(a) Within 30 days of the hearing completion date, the IHO shall issue a decision that is based on the evidence and consistent with the provisions of the approved state plan; the Act, as amended; federal vocational rehabilitation regulations, state regulations, and policies that are consistent with federal requirements, and shall provide to the appellant or, if appropriate, the appellant's authorized representative, and the Agency's authorized representative or the Agency's Office of General Counsel, as appropriate, a full written report of the findings of fact, conclusions of law, and any other grounds for the decision.

(b) The hearing completion date is the date upon which the IHO receives the transcript, if any was prepared, of the oral hearing, or, if no transcript was prepared, the date of the adjournment of the hearing.

(c) The decision shall address each issue considered by the IHO.

(d) The IHO may prescribe such remedies as are appropriate within the scope of, and permitted by, as applicable, Texas Labor Code, Chapters 352 and 355; the Act, as amended; the regulations of the Rehabilitation Services Administration of the U.S. Department of Education, 34 CFR Parts 361, 365, and 395; and the Agency's policies and rules.

(1) The IHO shall not award restitutionary, compensatory, or monetary relief, including monetary damages, to any party.

(2) The IHO shall not prescribe an action affecting the employment of an Agency employee.

§850.85. Finality of the Hearing Officer's Decision.

The decision of the IHO is the final decision of the Agency, and, if no timely motion for reconsideration is filed, becomes the final decision.

§850.86. Implementation of Final Decision.

If a party brings a civil action to challenge a final decision of an IHO, the final decision involved shall be implemented pending review by the court.

§850.87. Motion for Reconsideration.

(a) Any party to a hearing may file a motion for reconsideration within 20 days after the party is notified of the issuance of the IHO's decision. The motion shall be filed with the hearings coordinator within the Agency's Office of General Counsel.

(b) The motion for reconsideration shall specify the matters in the IHO's decision that the party considers to be erroneous. Any response to the motion for reconsideration shall be filed no later than 30 days after a party, or a party's attorney or representative, is notified of the IHO's issuance of the decision.

(c) The IHO shall rule on the motion for reconsideration no later than 15 days after receipt of the motion for reconsideration, or after receipt of the response to the motion for reconsideration, whichever comes later. If the motion for reconsideration is granted, the IHO issues a decision upon reconsideration within an additional 15 days. If the IHO fails to rule on the motion for reconsideration within 15 days, the motion for reconsideration is denied as a matter of law.

(d) Service. Service of the IHO's decision or of a motion for reconsideration or response under this section shall be made by any of the following means to a party, a party's attorney, or a party's representative:

(1) hand-delivery;

(2) courier-receipted delivery;

(3) regular first-class mail, certified mail, or registered mail;

(4) e-mail or facsimile transmission before 5:00 p.m. on a business day to the recipient's current e-mail address or telecopier number; or

(5) such other means as the IHO may direct.

(e) Date of service. The date of service is the date of hand-delivery, delivery by courier, mailing, e-mailing, or facsimile transmission, unless otherwise required by law. Unless the contrary is shown, a decision, motion, or response that is sent by regular first-class mail is presumed to have been received within three days of the date of postmark, if enclosed in a wrapper addressed to the recipient's last known address with return address to the sender, stamped with the appropriate first-class postage, and deposited with the US Postal Service on the date postmarked.

§850.88. Civil Action.

(a) Any party that disagrees with the findings and decision of an IHO has a right to bring a civil action in any court of competent jurisdiction without regard to the amount in controversy, consistent with 34 CFR §361.57(i).

(b) An individual must initiate a civil action for review of an IHO's decision by filing a petition not later than the 30th day after the date on which the decision that is the subject of complaint is final and appealable.

§850.89. Computation of Time.

(a) In computing any period of time prescribed or allowed by the rules in this subchapter, by order of an IHO, or by any applicable statute, the day of the act, event, or default after which the designated period of time begins to run is not included.

(b) Unless otherwise provided by the rules in this subchapter, the last day of the period so computed is included, unless it is a Saturday, Sunday, or legal holiday, in which event the period runs until the end of the next day that is not a Saturday, Sunday, or legal holiday. Saturdays, Sundays, and legal holidays shall not be counted for any purpose in any time period of five days or fewer.

(c) In computing the time periods required for filing a motion for reconsideration, as set forth at §850.87 of this subchapter (relating

to Motion for Reconsideration), and for appealing a final decision of an IHO to a court, as set forth at §850.88 of this subchapter (relating to Civil Action), Saturdays, Sundays, and legal holidays are included.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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SUBCHAPTER E. VOCATIONAL REHABILITATION SERVICES APPEALS AND HEARING PROCEDURES

DIVISION 1. GENERAL RULES

40 TAC §§850.60 - 850.84

The repeals are proposed under the authority of the Rehabilitation Act of 1973, as amended (29 USC §701 et seq.), and regulations of the U.S. Department of Education, 34 CFR Parts 361, 363, 367, 395, and 397. Texas Labor Code §352.101(b)(5) requires TWC to recommend the adoption of any rules necessary to implement the requirement to integrate the VR programs. Texas Labor Code §301.0015 and §302.002(d) provide TWC with the authority to adopt, amend, or repeal such rules as it deems necessary for the effective administration of TWC services and activities.

The proposed repeals affect Title 4, Texas Labor Code, Chapters, 301, 302, 352, and 355.

§850.60. Purpose.
§850.61. Legal Authority.
§850.62. Definitions.
§850.63. Filing a Request for Review.
§850.64. Time for Hearing.
§850.65. Assignment of Impartial Hearing Officer.
§850.66. Powers and Duties of Impartial Hearing Officer.
§850.67. Substitution of Impartial Hearing Officer.
§850.68. Reasonable Accommodations.
§850.69. Appearance of Parties at Hearings; Representation.
§850.70. Failure to Attend Hearing and Default.
§850.71. Witness Fees.
§850.72. Prehearing Conferences.
§850.73. Dismissal Without Hearing.
§850.74. Conduct of Hearing.
§850.75. Order of Proceedings.
§850.76. Rules of Evidence.
§850.77. Transcription of Proceedings.
§850.78. Prepared Testimony.
§850.79. Pleadings.
§850.80. Continuance.
§850.81. Motion for Reconsideration.
§850.82. Civil Action.
§850.83. Mediation Procedures.
§850.84. Computation of Time.

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DIVISION 2. DIVISION FOR BLIND SERVICES AND DIVISION FOR REHABILITATION SERVICES

40 TAC §§850.100 - 850.111

The repeals are proposed under the authority of the Rehabilitation Act of 1973, as amended (29 USC §701 et seq.), and regulations of the U.S. Department of Education, 34 CFR Parts 361, 363, 367, 395, and 397. Texas Labor Code §352.101(b)(5) requires TWC to recommend the adoption of any rules necessary to implement the requirement to integrate the VR programs. Texas Labor Code §301.0015 and §302.002(d) provide TWC with the authority to adopt, amend, or repeal such rules as it deems necessary for the effective administration of TWC services and activities.

The proposed repeals affect Title 4, Texas Labor Code, Chapters, 301, 302, 352, and 355.

§850.100. Purpose.
§850.101. Legal Authority.
§850.102. Definitions.
§850.103. Filing a Request for Review.
§850.104. Filings.
§850.105. Discovery and Mandatory Disclosures.
§850.106. Documentary Evidence and Official Notice.
§850.107. Impartial Hearing Officer Decision.
§850.108. Finality of the Hearing Officer's Decision.
§850.109. Implementation of Final Decision.
§850.110. Motion for Reconsideration.
§850.111. Appeal of Final Decision.

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SUBCHAPTER F. MEMORANDUM OF UNDERSTANDING

40 TAC §§850.130 - 850.132

The rules are proposed under the authority of the Rehabilitation Act of 1973, as amended (29 USC §701 et seq.), and regulations of the U.S. Department of Education, 34 CFR Parts 361, 363, 367, 395, and 397. Texas Labor Code §352.101(b)(5) requires TWC to recommend the adoption of any rules necessary to implement the requirement to integrate the VR programs. Texas Labor Code §301.0015 and §302.002(d) provide TWC with the authority to adopt, amend, or repeal such rules as it deems necessary for the effective administration of TWC services and activities.

The proposed rules affect Title 4, Texas Labor Code, Chapters, 301, 302, 352, and 355.

§850.130. Memorandum of Understanding Regarding Continuity of Care for Physically Disabled Inmates.

(a) The Agency [~~Texas Department of Assistive and Rehabilitative Services (DARS)~~] adopts by reference the memorandum of understanding (MOU) between the Texas Department of Criminal Justice, Texas Department of Aging and Disability Services, and Texas Department of State Health Services. The MOU contains the agreement required by Texas Health and Safety Code §§614.014 - 614.015 to establish the respective responsibilities of these agencies to institute a continuity of care and service program for offenders in the criminal justice system who are physically disabled, terminally ill, or significantly ill.

(b) The text of the MOU is in rule 37 TAC, Part 6, §159.19 (relating to Continuity of Care and Service Program for Offenders who are Elderly and Offenders with Physical Disabilities, or Significant or Terminal Illnesses [~~the Elderly, the Significantly or Terminally Ill and the Mentally Retarded~~]).

§850.131. Memorandum of Understanding Regarding the Exchange and Distribution of Public Awareness Information.

(a) The Agency [~~Texas Department of Assistive and Rehabilitative Services (DARS)~~] adopts by reference the memorandum of understanding (MOU) between the Texas Health and Human Services Commission [~~Rehabilitation Commission (now Texas Department of Assistive and Rehabilitative Services)~~], the Texas Department of Aging and Disability Services, and [~~Human Services (now Texas Department of Aging and Disability Services),~~] the Texas Department of State Health Services [~~Health (now Texas Department of State Health Services), the Texas Department of Mental Health and Mental Retardation (now Texas Department of Aging and Disability Services)~~].

(b) The MOU is the agreement required by Texas Human Resources Code §22.013, which authorizes and requires the exchange and distribution among the agencies of public awareness information relating to services provided by or through the agencies.

(c) The text of the MOU is located in 40 TAC, Part 1, §72.301 [~~of this title~~] (relating to Authorization and Requirement to Exchange and Distribute Public Awareness Information).

§850.132. Memorandum of Understanding Concerning Coordination of Services to Individuals with Disabilities [~~Disabled Persons~~].

(a) The Agency [~~Texas Department of Assistive and Rehabilitative Services (DARS)~~] adopts by reference the memorandum of understanding (MOU) between the Texas Health and Human Services Commission, the Texas Department of [~~Human Services (now Texas Department of~~] Aging and Disability Services[~~)~~], the Texas Department of [~~Health (now Texas Department of~~] State Health Services[~~)~~], the Texas Department of Family and Protective Services [~~the Texas Department of Mental Health and Mental Retardation (now Texas Department of Aging and Disability Services), the Texas Rehabilitation Commission (now Texas Department of Assistive and Rehabilitative Services), the Texas Commission for the Blind (now DARS' Division for Blind Services), the Texas Commission for the Deaf and Hard of Hearing (now DARS' Office for Deaf and Hard of Hearing Services)~~], and the Texas Education Agency.

(b) The MOU is the agreement required by Texas Human Resources Code §22.011, to facilitate the coordination of services to individuals with disabilities [~~disabled persons~~] by establishing the respective responsibilities of the agencies regarding the coordination of services to individuals [~~persons~~] with disabilities.

(c) The text of the MOU is located in 40 TAC, Part 1, §§72.201 - 72.212 [~~of this title~~] (relating to Memorandum of Understanding Concerning Coordination of Services to Persons With Disabilities).

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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